Supreme Court, U.S.
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Nos. 85-664

In the Supreme Court of the United States

OCTOBER TERM, 1985

FRANK YOUNG, COMMISSIONER OF FOOD AND DRUGS,
PETITIONER

v.

COMMUNITY NUTRITION INSTITUTE, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

JOINT APPENDIX

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PETITION FOR A WRIT OF CERTIORARI FILED OCTOBER 18, 1985
CERTIORARI GRANTED DECEMBER 9, 1985

In the Supreme Court of the United States

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UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 84-5223

(Civil Action No. 80-03110)

COMMUNITY NUTRITION INSTITUTE, ET AL.
APPELLANTS

v.

FRANK YOUNG, COMMISSIONER
FOOD AND DRUG ADMINISTRATION

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

RELEVANT DOCKET ENTRIES

Date	Filings – Proceedings
(B)04-13-84	Copy of notice of appeal and docket entries from Clerk, DC (n-4)
(B)04-13-84	Docketing fee was paid in the District Court on 04-11-84
(B)04-13-84	Docketing statement was mailed to counsel for appellants
(J)05-03-84	4 – Appellants' docketing statement (m-2)
(B)05-10-84	Clerk's order that a briefing schedule is set as follows: Appellants' brief and appendix (or record excerpts of Gen. Rule 17(c) transcripts) – 07-02-84: Appellee's brief – 08-01-84: Appellants' reply brief, if any – 08-15-84. Based upon the foregoing schedule, the Clerk shall include this case in the pool of cases available for selection on this Court's Nov./Dec., 1984 calendar.

(J)07-02-84	15 – Appellants' brief (m-2) (p-2)
(J)07-02-84	7 – Joint appendix (m-2) (p-2)
(J)07-27-84	4 – Appellee's motion for leave to file motion to extend time to file brief (m-27)
(V)08-01-84	Clerk's order that the motion, leave to file the instant motion is hereby granted, to extend briefing time is granted; and the briefing schedule is revised as follows: Appellee(s) brief – 08/22/84; Appellant(s) reply brief – 09/05/84. This disposition will not affect the calendaring of the instant case
(V)08-01-84	4 – Motion for extension of time to file appellee's brief (m-27) – per above order
(C)08-22-84	4 – Appellees' motion for leave to file motion to extend time to file brief (m-22)
(V)08-24-84	Clerk's order that the motion to extend briefing time is granted; and the briefing schedule is revised as follows: Appellee(s) brief – 08/29/84; Appellant(s) reply brief – 09/12/84. This disposition will not affect the calendaring of the instant case (Leave to file the instant motion is hereby granted)
(V)08-24-84	4 – Motion for extension of time to file appellee's brief (m-22) – per above order
(J)08-29-84	4 – Appellees' motion for leave to file brief in xerox form pending printing (m-29)
(J)08-29-84	1 – Notice of consent from parties to the filing of amicus curiae brief of the State of South Carolina
(J)08-29-84	15 – Brief of State of South Carolina as amicus curiae (m-29)
(V)09-05-84	Clerk's order granting appellee's motion for leave to file brief temporarily in photocopy form

(V)09-05-84	4 – Appellee's brief (m-29)
(J)09-11-84	4 – Appellants' motion for leave to file motion to extend time to file reply brief (m-11)
(J)09-25-84	15 – Appellee's brief (m-25)
(J)09-26-84	15 – Appellants' brief
(V)10-15-84	Clerk's order that the motion, leave to file the motion is hereby granted, to extend briefing time is granted; and the briefing schedule is revised as follows Appellant(s) reply brief – 10/15/84. This disposition will not affect the calendaring of the instant case. The Clerk shall retain the instant case in the pool of cases available for selection on this Court's November/December calendar
(V)10-15-84	4 – Motion for extension of time to file reply brief (m-11) – per above order
(V)10-15-84	15 – Appellants' reply brief (m-24)
(C)01-05-84 [sic]	CERTIFIED ORIGINAL RECORD (1 vol.)
(V)01-15-85	Clerk's order, sua sponte, that the following times are alloted for oral agrument Appellants – 25 minutes; Appellee – 25 minutes
(F)01-25-85	Argued before Mikva, Edwards, and Starr, CJs
(D)03-26-85	Opinion for the Court filed by Circuit Judge Starr.
(D)03-26-85	Judgment by this Court that the judgment of the District Court appealed from in this cause is hereby vacated and this case is remanded for further consideration, all in accordance with the Opinion for the Court filed herein this date.
(D)03-26-85	Mandate order.

(R)04-26-85	4—Appellant's motion to file bill of cost (m-24) [9]
(D)05-01-85	Per Curiam order, sua sponte, that the Opinion for the Court filed by Circuit Judge Starr on March 26, 1985 be, and hereby is amended. (SEE ORDER FOR DETAILS).
(R)05-10-85	15—Appellee's petition for rehearing and suggestion for rehearing en banc (m-10) [1]
(E)05-23-85	Per curiam order that appellee's petition for rehearing is denied. Mikva, Edwards and Starr, CJs.
(T)05-23-85	Per Curiam order, en banc, denying the suggestion for rehearing en banc; CJ Robinson, Wright, Tamm, Wald, Mikva, Edwards, Ginsburg, Bork, Scalia and Starr, CJs
(D)06-07-85	MANDATE ISSUED. Costs to be determined at a later date.
(E)06-13-85	Per curiam order denying appellants' motion to file bill of costs. Mikva, Edwards and Starr, CJs.
(R)06-28-85	Receipt from Clerk, District Court dated June 26, 1985 for certified original record (1 vol.)
(R)08-14-85	Notice from Clerk, Supreme Court advising that appellee has to and including October 20, 1985 to file a petition for writ of certiorari [1]
(C)10-28-85	Notice from Clerk, SC advising that petition for writ of certiorari was filed on Oct. 18 and docketed as SC No. 85-664

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 80-3110

COMMUNITY NUTRITION INSTITUTE, ET AL.
PLAINTIFFS

v.

JERE GOYAN, COMMISSIONER
FOOD AND DRUG ADMINISTRATION

RELEVANT DOCKET ENTRIES

Date	NR	Filing—Proceedings
1980		
Dec. 5	1	COMPLAINT, appearance.
Dec. 5		SUMMONS (3) and copies (3) of complt. issued. Da ser 12/9/80 deft ser 1/13/81
1981		
Jan. 23	2	INTERROGATORIES by pltffs. and document production requests to deft.
Feb. 9	3	ANSWER of deft. to the complaint. Appearance of Patricia J. Kenney.
Feb. 9		CALENDARED. CAL/N.
Feb. 25	4	MOTION by deft. for an enlargement of time.
Feb. 27	5	ORDER filed 2-26-81 granting motion of deft. for enlargement of time and allowing deft. until 3-8-81 to respond to pltffs. interrogatories and document production request. (N) JOHNSON, J.
Mar. 9	6	ANSWER of defts. to pltffs interrogatories; Exhibits.
Mar. 19	7	OBJECTIONS of defts. to pltffs. interrogatories. "Leave to file granted". (fiat) JOHNSON, J.

Mar. 27	8	ORDER filed 3-26-81 referring case, *sua sponte* to the Magistrate for discovery and pretrial. (N) JOHNSON, J.
Dec. 10	9	ORDER directing that discovery be completed by 2-5-82 and any dispositive motions be filed on or before 2-26-82; pretrail will be conducted not later than 3-31-82 and the trial will commence on April 19, 1982 at 10:00 A.M. (N) JOHNSON, J.
Feb. 19	10	ORDER setting trial on 4/19/82 and directing counsel to comply with certain requirements. (N) JOHNSON, J.
Feb. 25	11	REQUEST of deft. to substitute attached page which has been corrected to read Arthur Hull Hayes, Jr., Commissioner of Food and Drug Administration; attachment.
Feb. 25	12	STIPULATION and order that pltfs will file motion for summary judgment by 3/10/82. Defts. will file cross-motion for summary judgment and opposition to pltfs. motion by 4/9/82. Pltf. will file opposition to defts. cross-motion and a reply to defts. opposition by 4/19/82. Deft. will file reply to pltfs. opposition by 4/29/82. So Ordered. (N) JOHNSON, J.
Mar. 10	13	MOTION of pltffs. for summary judgment; statement of material facts; P&A's; Exhibits.
Apr. 9	14	MOTION of defts. for an enlargement of time.
Apr. 13	15	ORDER directing that deft. will file his dispositive motion and opposition to pltfs. motion for summary judgment by

4/15/82; that pltfs. will file their opposition to defts. motion and reply to defts. opposition by 4/26/82; and that deft. will file reply to pltfs. opposition, if necessary, by 5/6/82. (N) JOHNSON, J.

1982

Apr 15	16	MOTION of defts. to exceed the thirty-five page limit; Exhibit (Opposition).
Apr 15	17	MOTION of defts. to dismiss, or in the alternative, for summary judgment.
Apr 15	18	RESPONSE of defts. to pltffs. statement of material facts as to which there is no genuine issue.
Apr 15	19	STATEMENT of material facts by defts. as to which there is no genuine dispute.
Apr 21	20	ORDER granting motion of deft. to exceed the 35 page limit. (N) JOHNSON, J.
Apr 26	21	OPPOSITION of defts. to pltffs motion for summary judgment and memorandum of points and authorities in support of motion to dismiss, or in the alternative, for summary judgment; Appendix; statement of Leonard Stoloff; statement of Taylor M. Quinn; statement of Linda M. Quinones; Exhibits.
Apr 28	22	STIPULATION extending briefing schedule as pltffs. will file opposition to deft's motion and reply to deft's opposition on or before 5/7/82; deft will file a reply to pltff's opposition if necessary on or before 5/17/82, SO ORDERED. (FIAT)(N) JOHNSON, J.

May 14	23	MOTION of the State of South Carolina for leave to file an Amicus Curiae brief; Exhibit 1; Exhibit (amicus curiae brief).
May 17	24	STIPULATION filed 5/13/82 modifying the briefing schedule of both parties, (1) Plaintiffs will file their opposition to defts motion and reply to defts opposition on or before 5/17/82; (2) deft. will file a reply to pltffs opposition, if necessary, on or before 5/27/82. (fiat) JOHNSON, J.
May 17	25	OPPOSITION of pltffs. to defts. motion for summary judgment and reply to defts opposition to pltffs motion for summary judgment.
May 17	26	RESPONSE of pltffs. to defts. statement of material facts as to which there is no genuine dispute.
May 18	27	RESPONSE of defts. to motion for leave to file amicus curiae brief by the State of South Carolina.
May 27	28	RESPONSE of pltff. to motion and brief amicus curiae of the State of South Carolina.
Jun 8	29	MOTION of deft. for enlargement of time.
Jun 11	30	REPLY of defts. to pltffs. opposition to defts motion to dismiss or in the alternative, for summary judgment.
Jun 11	31	STIPULATION filed 6/10/82 allowing defts. until 6/8/82 in which to file a reply. approved. (N) JOHNSON, J.
Jun 23	32	NOTICE by defts. to substitute the attached pages 3,4,5,6,8,9, and 12 for those filed on June 11, 1982; attachments.

Aug 18	33	APPEARANCE of Jeffrey Gibbs as counsel for defts.
Dec 15	34	REQUEST by pltffs. for oral hearing.
1983		
Aug 30	35	NOTICE by deft. of filing of supplemental statement to update the Court on the status of requested exemptions from the FDA's action level for aflatoxin level in corn; additional statement of Taylor M. Quinn.
Sep 9	36	ORDER filed 9-6-83 granting motion of the State of South Carolina for leave to file an amicus curiae. (N) JOHNSON, J.
Sep 15		MOTION of pltf. and cross motion of deft. for summary judgment heard, argued and taken under advisement. (Rep. Gloria Wiliams) JOHNSON, J. (ml)
Dec 16	37	MOTION by pltfs. for an expeditious decision on cross-motions for summary judgment; attachment. (fs)
Dec 28	38	MOTION by deft. for enlargement of time to respond to pltffs' motion filed 12-16-83. (ml)
1984		
Jan 3	39	ORDER filed 12-30-83 that deft. shall have to and including 1-5-84 to respond to pltffs' motion filed on 12-16-83. (N) JOHNSON, J. (ml)
Jan 12	40	RESPONSE by deft. to pltfs' motion for an expeditious decision on cross-motions for summary judgment. "Leave to file granted." (fiat) JOHNSON, J. (signed 1-11-84) (ml)

Feb 16	41	ORDER filed 2/14/84 denying motion of pltfs. for summary judgment; denying motion of deft. to dismiss; granting motion of deft. for summary judgment; and dismissing case with prejudice. (N) JOHNSON, J. (ml)
Feb 23	42	MEMORANDUM OPINION filed 2-17-84. (N) JOHNSON, J. (ml)
Apr 11	43	NOTICE OF APPEAL by pltfs. from order entered 2/16/84 and memorandum opinion entered 2/23/84; $5.00 filing fee and $65.00 docketing fee paid and credited to U.S. Copies mailed to Patricia J. Kenney, Thomas Scarlett and David F. Weeda. (ef)
Apr 11		COPY of docket entries, notice of appeal transmitted as preliminary record to USCA. (USCA 84-5223) (ef)

[21 CFR PART 122]

POISONOUS OR DELETERIOUS SUBSTANCES IN FOOD

Notice of Proposed Rule Making

Elsewhere in this issue of the Federal Register the Commissioner of Food and Drugs is issuing proposed regulations concerning permitted levels of mercury in fish and shellfish (mollusks and crustaceans), lead in evaporated milk and evaporated skim milk, and aflatoxin in shelled peanuts and peanut products used as human foods. The Commissioner has concluded that Part 122, promulgated in an order published in the FEDERAL REGISTER of July 6, 1973 (38 FR 18096), should be expanded to deal with all poisonous or deleterious substances in food, including food-contact surfaces, pet food, and animal feed, to implement sections 402(a) and 406 of the Federal Food, Drug and Cosmetic Act.

Section 402(a) (1) of the act provides that a food shall be deemed to be adulterated:

If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.

Section 402(a) (2) of the act provides that a food shall be deemed to be adulterated:

(A) If it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of section 406, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408(a); or (C) if it is or it bears or contains any food additive which is unsafe within

the meaning of section 409: *Provided*, that where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity; or (D) if it is, or it bears or contains, a new animal drug (or conversion product thereof) which is insafe within the meaning of section 512.

Section 406 of the act permits the establishment of tolerances for added poisonous or deleterious substances in food; section 408 of the act permits the establishment of tolerances for chemicals in or on raw agricultural commodities; and section 409 of the act permits the establishment of tolerances for food additives.

The basic provision of the act dealing with poisonous or deleterious substances in food is section 402(a) (1) of the act, which applies to all poisonous or deleterious substances, whether they are naturally occurring or added. It is deliberately cumulative with the provisions relating to establishment of tolerences for food substances referenced in section 402 (a) (2) of the act and was retained from the Food and Drugs Act of 1906 because its language had been construed by the Supreme Court in United States v. Lexington Mill & Elevator Co., 232 U.S. 399 (1974). See Hearings on S. 2800 Before the Senate Committee on Commerce, 73d Cong., 2d Sess. 530 (1934). Its broad scope is shown by the fact that the related provisions in sections 406, 408(a), 409(a), and 512(k) of the act exempt a substance from section 402(a)(1) only if a regulation has been promulgated under the authority of those other sections.

Section 402(a) of the act distinguishes between naturally occurring and "added" substances and sets different standards for each. Naturally occurring substances are prohibited only if they render the food "ordinarily" injurious to health. Added substances are prohibited if they "may" be injurious to health; if such substances are necessary or unavoidable, special procedures are established by which they can be regulated.

"Added" is a statutory term of art encompassing all ingredients which are not inherent and intrinsic parts of a food. The term "added" was introduced into Federal food law in the drafting of the 1906 act when the U.S. Department of Agriculture (USDA) opposed a provision defining a food product as adulterated if it was injurious to health. The Department noted that such a provision would outlaw coffee, tea, and other foods containing deleterious ingredients as natural constituents. See the testimony of the Commissioner in Hearings on H.R. 6906, H.R. 8805, H.R. 8941, and S. 5 Before A Subcommittee of the House Committee on Interstate and Foreign Commerce, 74th Cong., 1st Sess. 58 (1935). To exempt such foods containing naturally occurring deleterious ingredients, the Senate committee considering the bill in 1906 adopted the word "added." See 40 Cong. Rec. 897 (1906). Although the word chosen implies that the statute is concerned with the act of addition, the legislative history makes clear that the term seeks rather to establish a standard based upon the necessary and inherent normal condition of the food.

Actions of the USDA after enactment of the 1906 act demonstrate that all contamination was regarded as "added." In 1914, the USDA announced that it had been investigating the presence of lead and arsenic in food, noting that such contaminants were "usually introduced into such products through the use of impure raw materials or from the apparatus or utensils employed in the processes of manufacture." The announcement further stated that "this

bureau holds that food containing arsenic or lead, added in any manner, is adulterated, in that it contains an added poisonous or deleterious ingredient which may render the product injurious to health." U.S. Department of Agriculture, Bureau of Chemistry, Service and Regulatory Announcements 312-313 dated June 23, 1914.

Throughout the hearings leading to the 1938 act, it remained clear that substance was "added" within the meaning of the statute whenever it was not inherent in nature, and not just when it was purposefully added. Thus, in explaining a proposed provision equivalent to the present section 402(a)(1) of the act, which removed the 1906 act's limitation to added ingredients, the Commissioner testified that the effect of eliminating the reference to added ingredients was to include deleterious ingredients "normal to the food product." Hearings on S. 2800, supra, at 528. The Commissioner's examples of added substances clearly included environmental and industrial contaminants. One example given of food containing an added poisonous substance was sugar contaminated by smoke from a nearby smokestack. Lead pipes, lead manufacturing equipment, and lead containers were also identified as sources of added poisonous substances. Hearings on H.R. 6906, supra, at 59-60; Hearings on S. 1944 Before a Subcommittee of the Senate Commerce Committee, 73d Cong., 2d Sess. 25, 27 (1933). The Commissioner testified at one point that some added poisonous or deleterious substances were "more or less universal," and at another time that "[t]here are very few things * * * in which you will not find contaminating products in some small degree." Hearings on S. 1944, supra, at 18; Hearings on H.R. 6906, supra, at 59. This emphasis on the ubiquity of added poisonous or deleterious substances clearly demonstrates that the term was understood to include all food contaminants.

The legislative history also identifies examples of foods naturally containing poisonous or deleterious substances and thus not subject to the "added" provisions of section 402(a)(1) of the act. These examples are Burma beans, which contain a glucoside that yields prussic or hydrocyanic acid; rhubarb, which contains oxalic acid; and coffee and tea. See Hearings on S. 1944, *supra*, at 17; Hearings on S. 2800, *supra*, at 29; Hearings on H.R. 6906, *supra*, at 58. Except for substances whose deleterious nature is inherent to the natural state of the food, and thus similar in origin to these examples, all poisonous and deleterious components are "added" within the meaning of the act. Moreover, when a naturally occurring poisonous or deleterious substance is increased to abnormal levels through mishandling or other intervening act, it is "added" to the extent of such increase.

Judicial decisions have recognized that the scope of the "added" provisions of the law extends to all poisonous or deleterious substances not inherently a component of the food. In the United States v. 1,600,800 Pounds of White Corn, Civil No.T-4173 (D.Kan., Dec. 18, 1970), the court held that aflatoxin in corn was an added poisonous or deleterious substance within the meaning of the act since aflatoxin is not a natural constituent of corn. In *United States v. 1200 Cans, Pasteurized Whole Eggs,* 339 F. Supp. 131, 136 (N.D. Ga. 1972), the court recognized that salmonella in eggs is an added poisonous or deleterious substance.

Section 406 was included in the 1938 act to permit the establishment of tolerences for added poisonous or deleterious substances which are required in the production of food or otherwise cannot be avoided by good manufacturing practice. A limitation may be placed upon such substances to the extent necessary for the protection of the public health. Although formal tolerances under section 406 have been used by the Food and Drug Administration, except for the tolerance for PCB's published

in the FEDERAL REGISTER of July 6, 1973 (38 FR 18096), informal action levels have frequently been utilized to implement this provision of the law and a number of those action levels exist today. In the past, such action levels have been issued through press releases and other public announcements but have not been published in the FEDERAL REGISTER or codified as regulations.

Section 408 was added to the act in 1954 to permit the establishment of tolerences for pesticide chemicals in or on raw agricultural commodities. This provision of the law was administered by the Food and Drug Administration (FDA) until the establishment of the Environmental Protection Agency (EPA) in 1970.

In 1958, Congress enacted the Food Additives Amendment, which affected the legal status of some of the contaminants previously regulated only as added poisonous or deleterious substances. The legislation was basically in two parts: first, a broad definition of "food additive" and a general prohibition of food additives not demonstrated to be safe; and second, a procedure by which the use of safe food additives could be approved. This two-part approach was the congressional answer to what was identified as a "dual problem." See H.R. Rep.2284, 85th Cong. 2d Sess.1 (1958). The first part of the problem was that under section 402(a)(1) and (2)(A) of the act, the burden is on the Government to show that a food substance is poisonous or deleterious. As the House Commerce Committee noted,"to prove an untested substance poisonous or deleterious may require approximately 2 years or more of laboratory experiments with small animals and during this period the Government cannot prevent the use of such a substance in food." The amendment therefore shifted the burden of proof in enforcement actions brought against food containing poisonous or deleterious substances to the food manufacturer.

The definition of "food additive" established in section 201(s) of the act is not limited to intentional additives. The

breadth of the language in section 201(s) of the act includes any food substance and excludes only those substances which cannot reasonably be expected to become a component of food. The statutory definition thus includes what are referred to as "incidental additives" as well as "intentional additives". See H.R. Rep. No. 2284, supra, at 3. Any added poisonous or deleterious substance in food, unless accidental and unforeseeable or specifically exempted by section 201(s) of the act, is a food additive. A food naturally containing a poisonous or deleterious substance becomes a food additive if it is not generally recognized as safe and is added to other food or undergoes processing. Food-packaging material may also contain food additives.The broad scope of section 201(s) of the act has been judicially recognized in United States v. Ewig Bros. & Co., Nos. 73-1008, 73-1454 (7th Cir., Aug. 28, 1974), and United States v. City Smoked Fish Co., Civil No. 33989 (E.D. Mich. 1970,1972) in which DDT in smoked fish was held to be a food additive. The court in United States v. Articles of Food, 370 F.Supp. 371 (E.D. Mich. 1974), held that substances migrating from pottery plates are food additives.

The Food Additives Amendment of 1958 was also intended to rectify the second part of the dual problem which was that "present law entirely prohibits the use of these additives even if their use at safe levels would advance our food technology and increase and improve our food supplies." H.R. Rep. 2284, supra, at 1-2. Section 409 of the act was enacted to permit issuing a regulation prescribing the conditions under which an additive may be safely used. Before any such regulation can be issued, the statute requires that the safety of the food additive be demonstrated. The statute also requires that the food additive accomplish a physical or other technical effect and requires the regulation to restrict use of the food additive to the lowest level necessary for that purpose.

When the Food Additives Amendment of 1958 was enacted, the provisions of section 406 of the act were not repealed. Although all added poisonous or deleterious ingredients are food additives, except when they appear in food accidentally and unforeseeably or are exempted under section 201(s) of the act because they are otherwise regulated under the act, the tolerance-setting provisions of section 406 of the act were left intact to deal with those unavoidably added poisonous or deleterious ingredients that could not meet the high standards for issuance of a regulation under the authority of section 409 of the act. A number of added poisonous or deleterious substances, which are also food additives within the meaning of section 201(s) of the act, are unavoidable but cannot meet the requirements for a section 409 regulation because their safety cannot be demonstrated and because they serve no functional purpose. A prominent example is lead, which was one of the contaminants most frequently mentioned in the legistative history of the 1938 act and one of the prime contaminants with which section 406 was enacted to deal. Lead cannot be the subject of a food additive regulation under section 409 of the act even at trivial levels because it serves no functional purpose. Section 406 of the act, therefore remains in force to control the use of such substances, since there would otherwise be no statutory means available to recognize their unavoidability and to exercise reasonable control over their presence.

Thus, there is nothing in the language of section 402(a)(2)(A) of the act to prevent issuance of a regulation under section 406 of the act for an added poisonous or deleterious substance that is also a food additive and for which no food additive regulation has been or can be promulgated. Section 402(a)(2)(A) of the act deems a food adulterated "if it bears or contains any added poisonous or deleterious substance (other than one which is * * * (ii) a food additive * * *) which is unsafe within the meaning

of section 406". If the parenthetical exception had been meant to prohibit issuance of section 406 tolerances for food additives, the exception would have been placed in section 406 of the act. Instead, the language of section 406 of the act allowing the Secretary of Health, Education, and Welfare to promulgate tolerances remains in full effect. Section 406 of the act must, of course, be read as having equal force and effect as the other parts of the statute.

The parenthetical exception was placed in section 402 of the act, the section dealing with the legal definitions of adulteration, rather than in section 406 of the act, the authority to promulgate tolerances, because the intention was to exempt a food additive from the provisions of section 406 of the act once a section 409 regulation has been promulgated. The parenthetical exception is thus similiar to the language in sections 406, 408(a), 409(a), and 512(k) of the act granting an exemption from section 402(a)(1) of the act if a regulation under one of those sections is in effect.

The correctness of that interpretation is confirmed by the language of the proviso in section 402(a)(2)(C) of the act. That proviso creates an exemption from the food additive provisions of the act for a pesticide in a processed food under certain circumstances. In doing so, the proviso refers to both sections 406 and 409 of the act. A reference to section 406 of the act would obviously not have been necessary to exempt a substance from the provisions of the act applicable to food additive if the language of section 402(a)(2)(A) of the act made the provisions of section 406 of the act inapplicable to food additives. Instead, because the proviso deals with a situation in which no section 409 regulation will be issued, the reference to section 406 of the act is necessary to afford complete exemption.

Similarly, when a tolerance for an unavoidable pesticide cannot be issued under the criteria of section 408 of the act, section 406 is available to control its use. Under the

Executive Order establishing it, the EPA promulgates tolerances under sections 406, 408 and 409 of the act for pesticides in or on food and the FDA is then responsible for enforcing those provisions.

The Commissioner proposes to establish procedures for controlling all poisonous or deleterious substances. Basic reliance on the provisions of section 409 for regulating use of such substances remains unchanged, and regulations issued under that authority are set forth in 21 CFR Part 121. However, when a food contaminant is unavoidable but cannot be approved under the criteria of section 409 of the act, a formal procedure is being proposed to control its use under the authority of sections 306, 402(a), and 406 of the act.

When a tolerance is established under the provisions of section 406, the act requires it to be set at the level necessary for the protection of the public health taking into account the extent to which the substance cannot be avoided and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

At times it will not be appropriate to establish a formal tolerance. The Commissioner is not required to establish a tolerance for every added poisonous or deleterious substance, as is indicated by the language of section 406 of the act recognizing that an adulteration charge can be made under section 402(a)(1) of the act when no tolerance is in effect. Section 306 of the act has long been interpreted to permit the Food and Drug Administration to establish action levels in implementing the adulteration provisions of the act. See United States v. Goodman, 486 F.2d 847 (7th Cir. 1973); United States v. Thriftimart, Inc., 429 F.2d 1006, 1011 (9th Cir. 1970); United States v. 1500 Cases More or Less, Tomato Paste, 236 F.2d 208, 211-12 (7th Cir. 1956); United States v. 449 Cases Containing Tomato Paste, 212 F.2d 567, 572-73 (2d Cir. 1954); United

States v. 133 Cases of Tomato Paste, 22 F.Supp.515, 516 (E.D. Pa. 1938); cf. United States v. Ewig Bros. & Co., supra.

When the factors required to be considered prior to promulgation of a section 406 tolerance are rapidly changing, it would be inappropriate to set such a formal tolerance. The procedures required by section 406 of the act, including a public hearing and requirement of substantial evidence to support the tolerance, contemplate ample evidence to consider, and a relatively stable situation where the evidence will be of more than transient significance and where the tolerance eventually promulgated will be appropriate for a relatively long period of time. For example, if industrial practices are improving so quickly that the extent to which the substance is unavoidable changes significantly from year to year, there is little justification for use of section 406 procedures. Similarly, if toxicological data are scanty or conflicting, but additional data are being developed, it would serve no good purpose to labor over an assessment of the existing data in a public hearing while ignoring the prospects of additional studies. The Commissioner therefore concludes that the structure and criteria of section 406 of the act indicate it is to be used primarily in relatively static circumstances.

When it is not appropriate to promulgate a tolerance under section 406, it may nevertheless still be appropriate to take some formal regulatory action to control use of a substance. In such circumstances, the Commissioner will consider promulgating an action level under authority of sections 306, 402(a), and 406 of the act.

Such action levels are similar to a formal tolerance in basis and effect. In setting an action level, the Commissioner considers evidence indicating when the presence of an added poisonous or deleterious substance may render food injurious to health, which is the standard in section 402(a)(1) of the act. In addition, the Commissioner takes into account the question of its unavoidability, a policy

embodied in section 406 of the act. Thus, an action level is based on the same criteria as a tolerance, except that an action level is temporary until the appearance of more stable circumstances makes a formal tolerance appropriate.

Particular problems are raised with respect to the use of pesticides, which frequently result in environmental contamination. Tolerances under section 406 of the act may be issued by EPA which allow for residues of pesticides in food, even though the pesticide itself is not registered by EPA for use with that particular crop.

An action level may also be established for a pesticide for which the EPA has not issued a tolerance under section 406 of the act. Because of their joint pesticide responsibilities under the act, the EPA and the FDA agree that both agencies have definite roles in respect to action levels for pesticides. Since action levels are an exercise of enforcement discretion, and since FDA is responsible for enforcement under the Executive Order establishing EPA, FDA is responsible for determining when an action level for a pesticide should be established and issuing such actions levels as regulations. Since action levels are similar to a formal tolerance in basis and effect, and since EPA has the expertise to establish pesticide tolerances, EPA is responsible for determining upon request from FDA, the appropriate level at which a pesticide action level is to be set.

Such tolerances or action levels properly recognize the problem of environmental contamination caused by drift of a pesticide from one area to another, or the persistence of the chemical in the environment over a period of time. In no instance, however, does any such action level or tolerance itself authorize use of any pesticide on a food crop for which it has not been registered by EPA. Except in the limited instances discussed below, no action level or other administrative action will be taken to permit the sale of food contaminated with a pesticide that has been used in any manner other than in strict accordance with the label directions approved by EPA.

The establishment of a tolerance or an action level does not authorize use of the particular poisonous or deleterious substance involved, or mean that any product containing up to that level of contamination is necessarily a lawful product. The failure to comply with the requirements of section 402(a)(4) of the act, which prohibits the preparation, packaging, or storage of food under insanitary conditions, is a separate violation of the act, even if the food itself does not violate any tolerance or action level for added poisonous or deleterious substances. Similarly, blending a contaminated food with a noncontaminated food, to produce a final product that falls within a tolerance or action level, is unlawful under the act and is prohibited by the proposed regulations.

The proposed principles and procedures set forth in Part 122 apply equally to imported food. Any food additive or pesticide intentionally used in or on imported food must be the subject of a regulation issued under section 408 or 409 of the act. Unavoidable added poisonous or deleterious substances may be the subject of a tolerance or action level issued under Part 122.

Because of enforcement practicalities, tolerances and action levels for imported food must be the same as for domestically produced food, although levels of unavoidable contamination may differ from country to country. For example, some pesticides are approved for use abroad because of conditions which justify their use, but are not registered for use in this country because those conditions do not exist here. In such a case, a regulation issued by EPA under section 408 or 409 of the act would apply to any food on which the pesticide was intentionally used. A tolerance may be issued by EPA or an action level by FDA, however, to be applied to food unavoidably contaminated by the pesticide. That tolerance or action level will be set at a uniform level for all food, including

domestic food. The establishment of the tolerance or action level would not authorize any use of the pesticide in this country, however.

The Commissioner intends to issue, by publication in the FEDERAL REGISTER, all existing action levels for unavoidable poisonous or deleterious substances as regulations in Part 122. In the interim, these publicly known action levels will continue in effect. Although the Commissioner intends to issue as regulations all new action levels as well, circumstances may require use of informal action levels pending issuance of final regulations. Such informal action levels will continue to be announced to the public.

Finally, the Commissioner recognizes that there may be some circumstances where it will be in the public interest to permit the marketing of food that is contaminated with a poisonous or deleterious substance, even though the contamination may have occurred through unlawful or other avoidable misuse of the substance and thus the food would not be eligible for a tolerance or action level. This would occur where a large amount of food is contaminated, resulting in a substantial adverse impact on the national food supply, and all available toxicological data indicate that no significant health hazard is involved. Accordingly, the proposed regulations provide a public procedure whereby, under such circumstances, the Commissioner may permit the marketing of such food, as an exemption from the usual rules that would be applicable. Any such exemptions would be limited to a single occurrence and would be decided on an ad hoc basis after public consideration of the issues involved.

The proposal also prescribes a method of issuing regulations to deal with foods containing naturally occurring poisonous or deleterious substances. Where appropriate, the Commissioner may identify foods which, because of their inherent components, are deemed to be adulterated

within the meaning of section 402(a)(1) of the act. These regulations would, of course, not constitute a complete list of such foods.

In the FEDERAL REGISTER of September 23, 1974 (39 FR 34172), the Commissioner consolidated existing regulations on substances prohibited from use in food in a new § 121.106 (21 CFR 121.106). Prohibited food additives will continue to be listed in Part 121, and Part 122 will be used only to identify foods prohibited even when not used as food additives. Since neither of these lists is exhaustive, the appearance of a food or of a poisonous or deleterious substance on one of the lists while not on the other does not constitute a determination that it should not appear on the other.

In addition, the proposal creates a method whereby interested persons can petition the Commissioner to establish a tolerance, action level, or other regulation under this part. Petitions adequately supported would be published in the FEDERAL REGISTER for comment.

No action is proposed for polychlorinated biphenyls (PCB's) (21 CFR 122.10) except recodification as § 122.100. The renumbered section is set forth in its entirety as part of the revision for the convenience of the reader. Additionally, paragraph (a)(9) of that section was stayed by an order published in the FEDERAL REGISTER of August 24, 1973 (38 FR 22792).

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 306, 402(a), 406, 408, 409, 701(a), 52 Stat. 1045-1046 as amended, 1049, 1055, 68 Stat. 511 as amended; 72 Stat. 1785-1788 as amended; 21 U.S.C. 336, 342(a), 346, 346(a), 348, 371(a)) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes that Part 122 be revised to read as follows:

PART 122 – POISONOUS OR DELETERIOUS SUBSTANCES IN FOOD AND FOOD-PACKAGING MATERIAL

Subpart A – Definitions and Procedures

Sec.
122.3 Definitions:
122.4 Establishment of regulations:
122.5 Petitions.
122.6 Added poisonous or deleterious substances.
122.7 Unavoidablity.
122.8 Exemptions.

Subpart B – Tolerances for Added Poisonous or Deleterious Substances

122.100 Polychlorinated biphenyls (PCB's).

AUTHORITY: Secs. 306, 402(a), 406, 408, 409, 701, 52 Stat. 1045-1046 as amended, 1049, 1055-1056 as amended, 68 Stat. 511, as amended; 72 Stat. 1785-1788 as amended (21 U.S.C. 336, 342(a), 346, 346(a), 348, 371).

Subpart A – Definitions and Procedures

§ 122.3 Definitions.

(a) "Act" means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms contained in section 201 of the act are applicable to such terms when used in this part.

(c) A "naturally occurring poisonous or deleterious substance" is a poisonous or deleterious substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other handling or contamination.

(d) An "added poisonous or deleterious substance" is a poisonous or deleterious substance that is not a naturally occurring poisonous or deleterious substance. When a naturally occurring poisonous or deleterious substance is

increased to abnormal levels through mishandling or other intervening act, it is an added poisonous or deleterious substance to the extent of such increase.

(e) "Food" includes human food, substances migrating to food from food-contact articles, pet food, and animal feed.

§ 122.4 Establishment of regulations.

(a) When appropriate under the criteria of § 122.6, a tolerance for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in Subpart B of this part under the provisions of section 406 of the act. A tolerance may be established at the level of zero.

(b) When appropriate under the criteria of § 122.6, an action level for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in Subpart C of this part to define the level of contamination at which a food will be deemed to be adulterated under section 402(a)(1) of the act. An action level may prohibit any detectable amount of the substance in food.

(c) A regulation may be estabished in Subpart D of this part to identify a food containing a naturally occurring poisonous or deleterious substance which will be deemed to be adulterated under section 402(a)(1) of the act. These regulations do not constitute a complete list of such foods.

§ 122.5 Petitions.

The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may issue a proposal to establish, revoke, or amend a regulation under this part. Any such petition shall include an adequate factual basis to support the petition, shall be in the form set forth in § 2.65 of this

chapter, and will be published in the FEDERAL REGISTER for comment if it contains reasonable grounds for the proposed regulation.

§ 122.6 Added poisonous or deleterious substances.

(a) Use of an added poisonous or deleterious substance, other than a pesticide chemical, that is also a food additive will be controlled by a regulation issued under section 409 of the act when possible. When such a use cannot be approved under the criteria of section 409, or when the added poisonous or deleterious substance is not a food additive, a tolerance or action level may be established pursuant to the criteria established in paragraphs (b) and (c) of this section. Use of an added poisonous or deleterious substance that is also a pesticide chemical will ordinarily be controlled by a regulation issued under section 406, 408, or 409 by the U.S. Environmental Protection Agency (EPA). When such a regulation has not been issued, an action level for an added poisonous or deleterious substance that is also a pesticide chemical may be established at a level specified by EPA pursuant to the criteria established in paragraph (c) of this section.

(b) A tolerance for added poisonous or deleterious substance in any food may be established when the following criteria are met:

(1) The substance cannot be avoided by good manufacturing practice.

(2) The tolerance established is sufficient for the protection of the public health, taking into account the extent to which the presence of the substance cannot be avoided and the other ways in which the consumer may be affected by the same or related poisonous or deleterious substances.

(3) No technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance established. Examples of changes that might affect the appropriateness of the tolerance include anticipated improvements in good manufacturing practice that would change the extent to which use of the substance is unavoidable and anticipated studies expected to provide significant new toxicological or use data.

(c) An action level for an added poisonous or deleterious substance in any food may be established when the criteria in paragraph (b) of this section are met, except that technological or other changes that might affect the appropriateness of the tolerance are foreseeable in the near future. An action level shall cease to be enforced and shall be revoked when a tolerance for the same substance and use has become effective.

(d) Tolerances will be established under authority appropriate for action levels as well as under authority appropriate for tolerances. In the event the effectiveness of a tolerance is stayed pursuant to section 701(e)(2) of the act by the filing of an objection and request for hearing, the order establishing the tolerance shall be deemed to be an order establishing an action level until final action is taken upon such objection.

§ 122.7 Unavoidability.

(a) Tolerances and action levels in this part are established at levels based on the unavoidability of the poisonous or deleterious substance concerned and do not establish a permissible level of contamination where it is avoidable.

(b) Compliance with tolerances and action levels does not excuse failure to observe either the requirement in section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act that food may not be prepared, packed, or held under insanitary conditions or the other requirements in this chapter that food manufacturers must observe current good manufacturing practices. Evidence obtained through factory inspection indicating such violation renders the food unlawful, even though the amounts of poisonous or deleterious substances are lower than the currently established tolerances or action levels. The manufacturer

of food must at all times utilize quality control procedures which will reduce contamination to the lowest level currently feasible.

(c) The mixing of a food containing a poisonous or deleterious substance in an amount above the tolerance or action level with another lot of food is not permitted and renders the final food unlawful regardless of the amount of poisonous or deleterious substance in the final food.

§ 122.8 Exemptions.

(a) The Commissioner may exempt from regulatory action and permit the marketing of any food that is unlawfully contaminated with a poisonous or deleterious substance if:

(1) He determines (i) based upon all available scientific evidence, that the food is safe for consumption and (ii) that destruction or diversion of the food involved would result in a substantial adverse impact on the national food supply.

(2) Such determination is published as a proposal in the FEDERAL REGISTER, with time for public comment whenever feasible. The time permitted for comment shall depend upon the degree of urgency required by the specific matter involved. In the event that no time for comment is feasible, the exemption may be issued as a final determination rather than as a proposal.

(3) The determination identifies the level of contamination allowed by the exemption, and the food to which it applies (e.g., the specific growing area or other identifying information). The exemption shall not apply to any other food produced in any other area or at any other time. Contaminated food not subject to the exemption will remain subject to regulatory action.

(b) Any person responsible for contamination of the food involved, or shipment of any such food in interstate commerce prior to the issuance of an exemption pursuant

to this section, shall remain subject to regulatory action pursuant to sections 302 (injunction proceedings) and 303 (penalties) of the act.

(c) In the case of a poisonous or deleterious substance which is a pesticide chemical, the level of contamination allowed by the exemption shall, upon request of the Food and Drug Administration, be specified by the Environmental Protection Agency pursuant to paragraph (a)(1)(i) of this section and promulgated by the Commissioner. No exemption for a pesticide chemical shall be promulgated without the concurrence of the Environmental Protection Agency.

Subpart B—Tolerances for Added Poisonous or Deleterious Substances

§ 122.100 Polychlorinated biphenyls (PCB's).

(a) Polychlorinated biphenyls (PCB's) are toxic, industrial chemicals. Because of their widespread, uncontrolled industrial applications, PCB's have become a persistent and ubiquitous contaminant in the environment. As a result, certain foods and animal feeds, principally those of animal and marine origin, contain PCB's as unavoidable, environmental contaminants. PCB's are transmitted to the food portion (meat, milk, and eggs) of food producing animals ingesting PCB contaminated animal feed. In addition, a significant percentage of paper food-packaging materials contain PCB's which may migrate to the packaged food. The source of PCB's in paper food-packaging materials is primarily of certain types of carbonless copy paper (containing 3 to 5 percent PCB's) in waste paper stocks used for manufacturing recycled paper. Therefore, temporary tolerances for residues of PCB's as unavoidable environmental or industrial contaminants are established for a sufficient period of time following the effective date of this

paragraph to permit the elimination of such contaminants at the earliest practicable time. For the purposes of this paragraph, the term "polychlorinated biphenyls (PCB's)" is applicable to mixtures of chlorinated biphenyl compounds, irrespective of which mixture of PCB's is present as the residue. The temporary tolerances for residues of PCB's are as follows:

(1) 2.5 parts per million in milk (fat basis).

(2) 2.5 parts per million in manufactured dairy products (fat basis).

(3) 5 parts per million in poultry (fat basis).

(4) 0.5 parts per million in eggs.

(5) 0.2 parts per million in finished animal feed for food-producing animals (except the following finished animal feeds: feed concentrates, feed supplements, and feed premixes).

(6) 2 parts per million in animal feed components of animal origin, including fishmeal and other by-products of marine origin and in finished animal feed concentrates, supplements, and premixes intended for food producing animals.

(7) 5 parts per million in fish and shellfish (edible portion). The edible portion of fish excludes head, scales, viscera, and inedible bones.

(8) 0.2 parts per million in infant and junior foods.

(9) 10 parts per million in paper food-packaging material intended for or used with human food, finished animal feed and any components intended for animal feeds. The tolerance shall not apply to paper food-packaging material separated from the food therein by a functional barrier which is impermeable to migration of PCB's.

(b) A compilation entitled "Analytical Methodology for Polychlorinated Biphenyls, February 1973" for determining compliance with the tolerances established in this

section is available from the Hearing Clerk, Department of Health, Education, and Welfare, Room 4–65, 5600 Fishers Lane, Rockville, MD 20852.

Interested persons may, on or before March 6, 1975, file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852 written comments (preferably in quintuplicate) regarding this proposal. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: November 29, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

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[21 CFR Part 122]

AFLATOXINS IN SHELLED PEANUTS AND PEANUT PRODUCTS USED AS HUMAN FOODS

Proposed Tolerance

Elsewhere in this issue of the FEDERAL REGISTER, the Commissioner of Food and Drugs is issuing proposed procedural regulations concerning the control of poisonous or deleterious substances in food. In accordance with those proposed procedures and principles, the Commissioner is issuing a proposal for a tolerance for aflatoxins in shelled peanuts and peanut products used as human foods.

Under certain environmental conditions, molds grow on and contaminate some of the foods we eat. Historically, mold contamination of food has been considered as an aesthetic problem; however, there have been numerous instances where consumption of moldy food or feed resulted in illness or death to humans or animals (references 1,2,3, and 4). In some of these cases, it was determined that the

cause was certain toxic chemical compounds produced by the molds. These compounds are known as mycotoxins (*mykes,* from the Greek, meaning mold). There are many known mycotoxins, but only a few have been found as food contaminants (reference 4).

The recent concern over mycotoxins was brought about by the discovery in the early 1960's of a specific group of mycotoxins known as aflatoxins (reference 1). The aflatoxins are chemically related substances produced by the common molds *Aspergillus flavus* (hence the name aflatoxins, from A. *flavus* toxins) and by *Aspergillus parasiticus.* The term "aflatoxins" also refers to a number of other related chemicals, which either are of synthetic origin or are produced biologically by animals fed aflatoxins. In this document, the terms "aflatoxin" and "aflatoxins" will include only the four common mold-produced aflatoxins known as B_1, B_2, G_1, and G_2.

Aflatoxims may contaminate foods whenever the producing molds grow on foods under favorable conditions of temperature and humidity. The presence of an aflatoxin-producing mold on a food does not necessarily imply the presence of the aflatoxins. Conversely, the absence of obvious growth of an aflatoxin-producing mold does not mean the absence of the toxins, since aflatoxins may be produced when there is little evident mold growth. Furthermore, aflatoxins may remain in a food product after processing has obscured or otherwise eliminated visible mold (references 3 and 4). Under laboratory conditions, a large number of foods can support the growth of aflatoxin-producing molds; under natural conditions in the field, natural competition determines which molds will grow and which mycotoxins will be produced. Corn, barley, copra, cassava, tree nuts, cottonseed, peanuts, rice, wheat, and grain sorghum are subject to natural aflatoxin contamination (reference 4). In

the United States, aflatoxins have been detected only in corn, figs, grain sorghum, cottonseed, certain tree nuts, and peanuts (reference 5).

Aflatoxins are present in peanuts and peanut products because of these contaminating molds. They are, therefore, added substances within the meaning of the Federal Food, Drug, and Cosmetic Act. The meaning of that term is discussed in detail in the preamble to the proposed procedures and principles for the control of poisonous and deleterious substances published elsewhere in this issue of the FEDERAL REGISTER.

The Commissioner has a two-fold concern with aflatoxins. First, animals fed aflatoxins are subject to acute tonic effects. Second, and of primary concern, data which indicate that these substances, particularly aflatoxin B_1, found in some species of test animals are among the most potent liver carcinogens known (references 1, 2, and 3).

The acute toxic effects of the aflatoxins are of little concern in the United States, since our agricultural and marketing processes assure that heavily molded food, which might contain levels of aflatoxins associated with such effects, does not enter the human food chain. Of great concern is the effect of long-term, low-level ingestion (i.e., chronic toxicity effects), particularly the carcinogenic effects (references 6, 7, and 8).

While there is no direct evidence that aflatoxins are a cause of liver cancer in man in the United States, their extreme potency as hepatocarcinogens in some animal species does furnish a foundation for the Commissioner's concern. The carcinogenicity of aflatoxins has been demonstrated in rats, monkeys, rainbow trout, ducks, ferrets, and mice (references 6, 7, and 8).

Aflatoxin carcinogenesis has been studied most extensively in rats. There have been several experimental studies with rats, and liver carcinomas have been produced in a number of different strains (reference 7).

In one study, highly purified aflatoxin B_1 was fed continuously to 25 rats for a period of 68-80 weeks. The level of aflatoxin in the diet was 15 parts per billion (ppb). All 25 rats developed liver carcinoma (reference 9). In a later study with the same strain of rat, liver carcinoma was produced in 2 out of 22 rats exposed for 105 weeks to a diet containing only 1 ppb aflatoxin B_1 (reference 9). These two studies demonstrate the extreme potency of aflatoxin B_1 as a liver carcinogen; however, other experimental studies furnish evidence that there are marked differences in the incidence of liver carcinomas in rats produced by various levels of aflatoxins depending on such variables as composition of the diet, age of the test animals, strain of rats used, and length and type of exposure (reference 7). The extreme difficulty in drawing conclusions from all of these studies is indicated by one study in which one strain of rat exposed to aflatoxins at a level of 80 ppb for 90 weeks suffered some liver damage, but no cancer (reference 10).

Liver cancer has been produced by ingestion of aflatoxins in three Macaque monkeys. One was exposed to an average of 0.02 milligram per kilogram (mg/kg) body weight daily for 5½ years. The other two were exposed to an average of 0.06 mg/kg body weight for 6 years (reference 8).

Epidemiological studies bearing on the possible effects of aflatoxin in man have been performed on specific population groups in Southeast Asia and Africa, where there is a known high incidence of primary liver cancer (references 8 and 11). In these areas, the climate and agronomic practices were expected to be conducive to production of aflatoxins in food. In one of the areas studied, 95 percent of the corn and 80 percent of the peanut samples had average aflatoxin levels around 100 ppb. In another area, 20 percent of the food staples contained aflatoxin levels averaging 300 ppb. In a third area,

there was a high incidence (7 percent) of low levels (3-4 ppb) of aflatoxins in family meals. The result of these studies is an indication of a general correlation between the incidence of primary liver cancer in humans and the exposure to aflatoxins (reference 11).

No epidemiological studies of these types have been carried out in the United States. However, primary liver cancer is a minor form of cancer in the United States, accounting for about 0.7 percent of all cancer cases (reference 12). In addition, cancer rates in those areas of the United States where climatic conditions are most conducive to aflatoxin contamination (i.e., the southeastern states) do not differ significantly from other areas (reference 13). Domestic profiles for primary liver cancer differ in sex and age from those observed in "high incidence" countries (reference 13). One study in a major city in the United States shows some degree of correlation between primary liver cancer and alcoholism (reference 14).

Thus, while it is not certain that aflatoxins are a cause of primary liver cancer in the United States, the Commissioner concludes that the observations of severe carcinogenic effects in experimental animals and positive correlations between dietary aflatoxins and primary human liver cancer seen in other parts of the world are sufficient justification to regard aflatoxins as poisonous or deleterious substances and to take actions to hold human exposure to aflatoxins in the United States to the lowest level possible. Shortly after the discovery of the presence of aflatoxins in peanuts (reference 15), the Food and Drug Administration (FDA) began a program for their control (references 5 and 16). In 1965, the FDA established an informal action level of 30 ppb total aflatoxins. In 1969, it was reduced to the current level of 20 ppb total aflatoxins.

The informal action level of 20 ppb has been applied to all affected commodities. As more is learned about the extent to which contamination of foods by aflatoxins can be avoided, FDA will systematically and formally adjust its

action level to reflect this new knowledge either as an action level or tolerance. Since different agricultural products become contaminated in different ways and since the potential for removing contamination during processing differs from one product to another, the extent to which aflatoxin contamination can be avoided is commodity dependent. Action levels or tolerances will be established, then, on a commodity-by-commodity basis. In each case, the action level or tolerance will be consistent with the concept that the total human exposure to aflatoxins must be as low as possible.

At the present, there exists a body of information upon which to judge the extent to which aflatoxin contamination can be avoided in shelled peanuts and peanut products used as human food, and a reconsideration of the action level for these commodities is in order. FDA is in the process of collecting relevant information on other affected commodities. When this information becomes adequate in scope and content, adjustments in the acceptable level will be made for each of the other affected products. Until then, the 20 ppb action level will be maintained.

It is now known that aflatoxins can contaminate peanuts during any of several stages: growth, harvest, shipment, or storage. Whether mold develops at any or all of these stages depends on such factors as kernel damage, temperature, moisture, and availability of oxygen (references 17 and 18).

Although aflatoxin contaminated peanuts can be found prior to harvest, the major point of contamination, by all available evidence, is the curing process. Once mold invasion takes place, aflatoxins may be produced unless the moisture content is rapidly reduced to a level unfavorable to mold growth (references 17, 18, and 19).

Employed properly, artificial drying is an effective way to control contamination; nevertheless, large quantities of peanuts are still dried naturally, thereby risking contamination due to unfavorable weather conditions

(reference 17). Fuel shortages are apt to increase the problem, since artificial drying may give way to natural, open air drying practices.

Damage to the peanut shell may be one of the most significant factors leading to mold growth and aflatoxin contamination. It has been demonstrated that the removal of damaged kernels can lead to a major reduction in the aflatoxin levels in peanuts (references 15 and 19). Insect infestation is one source of damage; however, many kernels are damaged as the result of mechanical harvesting techniques (reference 17). Once the natural barrier imposed by the shell is breached, mold invasion can begin.

Fungicides, crop rotational practices, and other good agronomic practices can ameliorate the problem to an extent (reference 17). It is impossible at this time totally to eliminate all of the breakdowns that can occur in the total process of growing, harvesting and storing peanuts. Adverse weather, insects, improper harvesting methods, and general ignorance of the problems and solutions will be with us for some time to come. Thus, in practice, the complete prevention of mold growth and aflatoxin production in peanuts appears unattainable at the present time.

Processors of shelled nuts can eliminate some contaminated material by using a number of standard manual, mechanical, and electronic sorting procedures. Although these procedures were originally designed to remove the damaged, discolored, and immature nuts which affect appearance and flavor, they have been useful in removing aflatoxin-containing peanuts, since contamination is often associated with such peanuts (references 15, 20 and 21). Sorting does have a major limitation in that intact, sound, mature kernels can contain aflatoxins (reference 22). Due to this and other as yet unidentified reasons, there is a limit, not easily definable, to the effectiveness of sorting techniques.

The ordinary process of roasting peanuts results in some reduction of average aflatoxin level, but complete elimination of aflatoxins cannot be accomplished by the process (reference 23).

In order to detect the presence of aflatoxins in peanuts, it is necessary to have analytical methods of adequate sensitivity and specificity. Such methods are available and their effectiveness has been demonstrated by interlaboratory collaborative studies. These are now official methods of the Association of Official Analytical Chemists (AOAC) (references 3, 24, and 25). AOAC Method I can be used to detect aflatoxins B_1, B_2, G_1, and G_2 in peanut products at levels as low as 1-2 ppb (total aflatoxins). AOAC Method III, although not as accurate as Method I at low levels (2-10 ppb), is much more rapid and is used as an industrial quality control method (references 25, 26, and 27). Tests for confirmation of indentity of measured aflatoxins B_1 and G_1 have also been studied collaboratively and are official AOAC (reference 24).

While the analytical methods are a source of variability in the assay for aflatoxins, the greatest source of variability is sampling. Contamination is usually confined to a small number of kernels and there is thus no practical sampling plan which can assure that a sample is truly representative of the entire lot under investigation. Therefore, any practical sampling plan must be based on certain distribution assumptions and can assure only a limited level of confidence that a particular sample is representative of a lot (reference 28).

FDA regulation of finished peanut products has been only a part of the total control picture. The U.S. Department of Agriculture (USDA), through its Peanut Marketing Agreements, had been involved in establishing and maintaining sampling and analysis procedures designed to remove lots of peanuts showing visible A. *flavus* mold and lots of aflatoxin-contaminated raw peanuts

prior to finished product manufacture (references 16 and 29). FDA has been involved in this program on a consulting basis and receives yearly, for analysis and evaluation, the USDA reports of analyses of raw, shelled peanuts (reference 30). This program requires that all shelled peanuts offered for sale to manufacturers or wholesalers be sampled and analyzed for aflatoxins by a laboratory certified as competent by the Peanut Administrative Committee (references 5 and 21). A negative certification means that the sample assay is not over 25 ppb total aflatoxins (reference 21).

Once a lot of peanuts is sampled and assayed, it may or may not be tested again as practices vary among manufacturers. Some manufacturers do maintain their own in-house laboratories, or contract for testing services through independent or government laboratories. Others perform no further testing at all, relying on the processing procedure to remove the aflatoxins.

Since the inception of this system of controls, sampling and analysis by FDA has turned up few violative samples of finished peanut products (reference 5). FDA surveillance, however, has been limited. In 1973, the agency conducted its first large survey of the nation's peanut products. This was done to determine the nature of the quality control procedures being utilized by manufacturers to remove contaminated peanuts and the effectiveness of these procedures (reference 31).

The survey was also used to determine the distribution of various levels of aflatoxins in the nation's peanut product supply. These survey data are used as one of the considerations in establishing a tolerance for aflatoxins in peanut butter and other peanut products. All analytical data gathered in surveys of this type and reported here include the errors associated with sampling and analysis of aflatoxins.

The FDA survey encompassed 146 peanut butter and/or peanut product manufacturers. Of prime concern was geographical and size distribution, with the greater emphasis on smaller concerns where the poorest operating procedures and quality control were presumed to exist. A checklist was provided to each FDA inspector to ensure uniform reporting and data retrieval. From the 146 establishments, 361 samples of peanut butter and other finished peanut products (generally unground) were collected.

Aflatoxins levels above the action level (total aflatoxins, 20 ppb) were found in 4 percent of the 141 peanut butter samples and 2 percent of the 220 samples of unground peanuts. These samples with levels above the action level came from 5 percent of the establishments inspected. Detectable aflatoxins (greater than approximately 1 ppb) were found in 25 percent of the peanut butter samples and 10 percent of the unground peanut samples. These samples came from 22 percent of the establishments inspected. There is a large error inherent in sampling unground nuts for aflatoxins compared to the blended product, peanut butter. This precluded drawing a statistically valid inference that the incidence of aflatoxins in unground nuts is lower than that in peanut butter.

The data were examined for possible correlations between aflatoxin findings and size of the establishment, between aflatoxin findings and manufacturing practices related to control of aflatoxin contamination, and between aflatoxin findings and the aflatoxin level in the raw peanuts used.

Aflatoxin levels above 20 ppb were found only in the small and medium size establishments; however, 50 percent of the 10 largest establishments provided samples with detectable aflatoxin, compared to 23 percent of the 136 small and medium size establishments (reference 31).

No correlation between establishment size and incidence and degree of contamination could be found for the establishments inspected.

In the instances where aflatoxin contamination was found in the consumer product, there was no obvious correlation between the levels of aflatoxin found and the various manufacturing practices used (reference 31). The same observation holds for both peanut butter and unground peanuts.

There were indications that the processing of peanuts could result in a reduction of aflatoxin level to a trace of nondetectable level. However, the level of aflatoxin in raw peanuts was not consistently related to the level in the consumer product. In 15 instances, the level in the consumer product was higher than that found in raw peanuts. This result emphasizes the difficulty in obtaining a representative sample of the granular product (raw peanuts), as aflatoxin contamination may be extremely heterogeneous within a lot (reference 31).

The presence of detectable levels of aflatoxins in consumer products could result either from faulty application of the reported inspection and sorting practices or a peculiarity in the nature and distribution of the contamination. The latter possibility has some justification since aflatoxin has been found in otherwise sound, undamaged kernels.

One important conclusion which derives from all of these findings is that current manufacturing capabilities cannnot consistently assure the complete elimination of aflatoxin-contaminated peanuts from a lot during processing. What level can be consistently reached is determined by a detailed consideration of the FDA and other survey data, including those gathered by the USDA analyses of peanut butter produced under government contract and those collected by the Canadian Health Protection Branch (reference 30).

Thus, in determining an acceptable level for aflatoxins in shelled peanuts and other peanut products, the Commissioner considered all of the available information and sought to bring into balance four factors:

1.The need to minimize human exposure to aflatoxins;

2.The capabilities of sampling procedures and analytical methods to detect, measure and confirm the aflatoxins;

3.The capability of agricultural and manufacturing technology to prevent and remove contaminated peanuts; and

4.The need for the continued availability of a low cost protein source (i.e., peanuts (reference 32)).

Survey data (FDA, USDA, and Canadian) indicate that since 1971 an average of 93 percent of sampled peanut products contained aflatoxins below the 20 ppb level (references 30 and 31). The Commissioner concludes that current agricultural and manufacturing technology is capable of meeting a level below that which it is now being asked to meet. Although the immediate result of lowering the level may be the loss of a small percentage of the peanut supply, improved producer practices should compensate for any short-run loss.

Obviously, for complete protection, aflatoxins should be eliminated from food, but this is not presently feasible. Therefore, it is necessary for the Commissioner to weigh the consequences of possible levels above zero.

Setting a level at 5 or 10 ppb was considered by the Commissioner. Eleven of the 12 major U.S. manufacturers of peanut butter could meet a 10 ppb level in 90 percent of their products (reference 33). The Canadian government survey of 1972 indicated that 95 percent of the samples of peanut butter could meet this standard. However, there is year-to-year variability in aflatoxin contamination of the peanut crop. The FDA survey of 1973 evidenced the fact that only 89 percent of the peanut butter samples and 82 percent of the establishments surveyed

met a 10 ppb level. Of the 12 largest establishments surveyed, only seven met a 5 ppb limit in 90 percent of their samples (reference 33). There are also data showing that in some years only about 60 percent of the peanut butter produced met a 5 ppb level (reference 30). One bad crop year could effectively eliminate a large percentage of peanut products from the market. Thus, a move to 5 or 10 ppb could result in significant losses to producers, manufacturers, and consumers alike.

These increased losses of food would result in much higher prices (reference 33) or in unavailability of what is generally considered a highly nutritious and useful food.

Another important consideration concerns setting a tolerance at a level at which manufacturers have the capability to monitor their products during processing and ensure that the finished product complies with the tolerance. Manufacturers of peanut products now monitoring their production set analytical limits for their products in the range 5 to 10 ppb to ensure that their finished products do not exceed the current 20 ppb action level; this factor must be built into a quality control operation because of the large error associated with sampling and analysis. Setting a tolerance level of 5 to 10 ppb for aflatoxins in peanut products would have the effect of requiring manufacturers to employ an analytical limit of less than 1 to 5 ppb for quality control purposes. Because present sampling and analytical methodologies have considerable error at the 1-5 ppb range, analytical results obtained for such quality control samples would not accurately represent the production lot from which the sample was drawn. Therefore, the capability of manufacturers to control their production at these levels is extremely questionable, and to guard against the release of products containing levels of aflatoxins in excess of 5 or 10 ppb is not possible.

It would serve no useful purpose to establish a tolerance at a level at which current sampling and analytical procedures are such that compliance with the tolerance is unachievable.

In addition, because there is no direct evidence that aflatoxins cause cancer in man or of what may be the level of no effect, the Commissioner cannot conclude that there is any tangible gain from lowering the permissible level to either 10 or 5 ppb. Such uncertain benefit to the public health must be weighed against the clear loss of food that would result.

On the basis of these considerations, the Commissioner concludes that justification does not exist for implementing a maximum permissible level at either 10 or 5 ppb.

A level of 15 ppb represents a lowering of the level from the 20 ppb level which has stood since 1969. FDA survey data indicate that 93 percent of the lots of peanut butter and 97 percent of the lots of other peanut products could meet the 15 ppb level (reference 31).

Survey data from the the Canadian Government and from USDA show that, on the average, 97 percent of the lots of peanut butter sampled since 1971 could meet the proposed level (reference 30).

The Commisioner concludes that existing agricultural and industrial technology can combine to yield finished peanut products at or below a 15 ppb level without causing significantly increased losses of food. This level will also allow manufacturers to maintain capability for monitoring their products during processing with nearly as much reliability as could be attained with a 20 ppb level. At the same time, the lowering of the allowable level to 15 ppb will result in decreased human exposure to aflatoxins.

In setting a tolerance or action level, the Commissioner considers the other ways in which the consumer may be affected by the same substance or by other substances. Since there is no known acceptable level of intake of aflatoxins

and the proposed tolerance is set at the lowest practicable level, the existence of other poisonous or deleterious substances do not affect the level proposed for aflatoxin in shelled peanuts and peanut production.

The regulation also prescribes sampling and analytical methods by which compliance with the proposed limitation will be determined. Because of possible variation in the results obtained by the analytical method prescribed, the regulation provides that the average of duplicate analyses shall be used.

Taking into account (1) the fact that aflatoxins cannot be avoided by current agronomic and manufacturing processes; (2) the extent to which aflatoxins are unavoidable; (3) the data on the effects of aflatoxins; and (4) the other ways in which the consumer may be affected by aflatoxins and other substances, the Commissioner proposes to establish a tolerance for aflatoxins in shelled peanuts and peanut products used as human food, above which such products will be deemed unsafe within the meaning of section 406 of the act. Accordingly a tolerance of 15 ppb is proposed.

Pending a final regulation, FDA will continue to apply for enforcement purposes an action level of 20 ppb for aflatoxin in shelled peanuts and peanut products.

The Commissioner has considered promulgating the present proposal as an action level. Limiting an unavoidable aubstance through use of an action level, rather than a tolerance, is appropriate when changes are foreseeable in the near future that might affect the appropriateness of the limitation established. This, however, is not the case with aflatoxins. The Commissioner is unaware of any new or anticipated developments that would affect the proposed 15 ppb level in the near future. There are no new procedures pending, either agronomic or technical, that will alter the present unavoidability of aflatoxins. Furthermore, it is unlikely that any new pertinent information will become available in the near future.

Therefore, it is the Commissioner's preliminary conclusion that the most reasonable approach to regulating aflatoxin, in shelled peanuts and peanut products, would be a formal tolerance established under section 406 of the act. The Commissioner, however, specifically solicits comments on the question of whether any anticipated changes make an action level more appropriate.

REFERENCES

A copy of each reference document is on file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, and may be seen during working hours Monday through Friday.

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32. "Peanut Butter: Low Cost Nutrition" Consumers Reports, 37(5):286-288, May 1972.

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Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 306, 402, 406, 701, 52 Stat. 1045-1046 as amended, 1049, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948; 21 U.S.C. 336, 342, 346, 371) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes that Part 122 be amended by adding a new § 122.101 as follows:

§ 122.101 Aflatoxin in shelled peanuts and peanut products used as human food.

(a) A tolerance of 15 parts per billion (ppb) is established for total aflatoxins (B_1, B_2, G_1, G_2) in shelled peanuts and peanut products used as human food.

(b) Compliance with this section shall be determined as follows:

(1) A lot shall consist of a collection of primary containers or units of the same size, type and style produced under conditions as nearly uniform as possible, designated by a common container code or marking, or in the absence of common container code or marking, a day's production.

(2) (i) The sample for aflatoxin analysis of smooth peanut butter shall consist of a composition of 24 subsamples (primary units) randomly drawn from a lot.

(ii) For all other peanut products, the sample shall consist of a composite of 48 subsamples (primary units) randomly chosen from a lot, or if from a bulk lot, 48 1-pound subsamples.

(3) Composites shall be analyzed in duplicate using 50-gram portions from the lot sample by the methods of the Association of Official Analytical Chemists (AOAC), as described in "Official Methods of Analysis of the Association of Official Analytical Chemists," 11th Ed., Chapter 26, Secs. 26.015-26.020.[1]

(4) A lot does not comply with the tolerance established in paragraph (a) of this section when:

(i) The average value of the two analyses of the composite of randomly chosen subsamples is greater than 15 ppb total aflatoxins; and

(ii) The identity of aflatoxins in the analytical sample is confirmed by chemical derivative formation (AOAC, Official Methods of Analysis, 11th Ed., Chapter 26, Secs. 26.054-26.055).

Interested persons may, on or before March 6, 1975, file with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: November 29, 1974.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc. 74-28408 Filed 12-5-74;8:45 am]

[1] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

[4110 93]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[Docket No. 77N-0166]

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

POISONOUS OR DELETERIOUS SUBSTANCES

AGENCY: Food and Drug Administration.

ACTION: Final Rule.

SUMMARY: This rule establishes procedures for regulating food contaminants and naturally occurring poisonous or deleterious substances in food. This action is being taken to implement those provisions of the Federal Food, Drug, and Cosmetic Act that permit the Commissioner of Food and Drugs to set tolerances and action levels to control the levels of unavoidable contaminants in food. These procedures, which also permit the identification and listing of naturally occurring poisonous or deleterious substances in food, apply to all poisonous or deleterious substances in food, including food contact surfaces, pet food, and animal feed.

EFFECTIVE DATE: October 31, 1977.

FOR FURTHER INFORMATION CONTACT:

Caesar A. Roy, Bureau of Foods (HFF-310), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington. D.C. 20204 (202-245-1567).

SUPPLEMENTARY INFORMATION:

These regulations were proposed in the FEDERAL REGISTER of December 6, 1974 (39 FR 42746). Several comments were received in support of the proposed regulations; others supported the general approach but opposed specific provisions. The Commissioner's responses to most of the comments received are set forth below.

However, comments that concerned proposed § 122.7(c) of the regulations, which would codify the agency's prohibition against "blending" a food containing a poisonous or deleterious substance above the permitted tolerance with less contaminated food, have not yet been fully evaluated. The issue of "blending" remains under study within FDA, and the prohibition will not be codified at this time. Until the issue is resolved, the agency's long-standing prohibition against "blending" remains in effect.

When these regulations were proposed, regulations codified in 21 CFR Parts 121 and 122 (now Parts 109 and 170-189, recodification was published in the FEDERAL REGISTER of March 15, 1977 (42 FR 14302)) applied to food for human use as well as pet food and animal feed. Subsequently, regulations covering pet food and animal feed were recodified separately from the regulations covering human food. The pet food and animal feed regulations are now codified in 21 CFR Parts 509 and 570 (recodification from Parts 121 and 122 was published in the FEDERAL REGISTER of September 10, 1976 (41 FR 38618)). This document, therefore, establishes identical regulations in Parts 109 (food for human consumption) and 509 (pet food and animal feed). The changes in 21 CFR Part 181 were incorporated into Subchapter E for pet food and animal feed under 21 CFR 570.13.

1. Comments stated that FDA should never permit the sale of contaminated food.

The Commissioner advises that it is not possible to produce food or food ingredients that are entirely free from contamination by foreign substances or impurities. This is not a modern phenomenon. Wholesome foods have inevitably been the carriers of levels of contamination beyond the capability of contemporary processing methods to eliminate and sometimes even detect. At best, therefore, specifications for "food grade" substances can be established, as has been done in the Food Chemicals Codex, to ensure that only minimal levels of contaminating substances are present. Where more significant levels of contamination occur unavoidably, action levels or tolerances may be established under Part 109 (formerly Part 122), of the regulations to ensure the safety of the food.

2. One comment suggested that the label of a contaminated food bear the warning "hazardous to health."

The Commissioner advises that tolerances and action levels will be established at levels intended to ensure that food marketed is not hazardous to health. The suggested warning would therefore be unnecessary and inappropriate. If any food is found to be hazardous to health, FDA will not permit it to be distributed in interstate commerce.

3. A number of comments argued that the distinction in the act between "added" and naturally occurring poisonous or deleterious substances is a distinction between substances introduced into the food chain through the agency of man and those introduced through the force of nature.

The Commissioner concludes that there is no basis for basing a distinction between "added" and naturally occurring contaminants on the presence or absence of human intervention. If that distinction were to be adopted as the proper interpretation of the statute, it would be necessary to ascertain the precise means by which a contaminant was

introduced into the environment, often in historic time, before taking regulatory action. It makes little sense to argue that a contaminant that was introduced into the environment by man generations ago should be regarded differently from contamination caused, for example, by geological phenomena, such as contamination of water by mercury. There would be regulatory problems in trying to ascertain the role human activity played in introducing a contaminant. For example, in the case of contamination occurring through mercury leaching into water from geological sources, it would presumably be necessary to determine whether man's activities exposed more geological surfaces to the waters than would naturally have been exposed. Such an expensive and protracted inquiry would provide no additional information upon which to determine the level of contamination that can be safely tolerated. Moreover, there is nothing in the statute that suggests that the definition of an "added" poisonous or deleterious substance is related to human involvement.

4. One comment contended that the language "any poisonous or deleterious substance added to any food" in section 406 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346) contemplates addition through the agency of man since the term "added" is "used as an active verb."

The Commissioner notes that the comment discussed only the initial portion of section 406 of the act. The section goes on to identify two circumstances in which "added" poisonous or deleterious substances may be permitted: (1) Where the substance is "required in the production" of a food, and (2) or where the substance "cannot be avoided by good manufacturing practice." Although the language of the first circumstance connotes human action, the language of the second does not.

5. One comment stated that the legislative history of the act demonstrated that the term "added" poisonous or deleterious substances referred to substances that became

a component of food through the agency of man. In support of this contention, the comment quoted from the testimony of Walter Campbell, then Chief of the Food and Drug Administration, who was concerned with contamination resulting from the "development of the country and the extension of industrial activities." The comment also emphasized Mr. Campbell's examples of smoke contaminating sugar with arsenic and pesticides spray residues in support of its argument that the concept of "added" poisonous or deleterious substances was limited to food contaminants introduced into the environment by man. The comment also cited a 1934 Senate committee report that stated that the amended statute covered all contaminants "whether that constituent is added by man or put there by nature." In addition, the comment emphasized language in the report that stated "it is immaterial to the welfare of the consumer whether a poison in his food is introduced by artifice or occurs naturally." The comment argued that this testimony and committee report support the conclusion that the term "added" poisonous or deleterious substance pertains only to those substances for which human activity is responsible.

The Commissioner concludes that the legislative history cited in the comment does not support the contention that "added" poisonous or deleterious substances are only those that become a component of food through the agency of man. Industrial development was seen as leading to the appearance of additional contaminants, but there is nothing in the legislative history to suggest that the often remote human connection with food contaminants was to be the basis for permitting tolerances to be established. It is implausible that Congress would have intended that, before establishing a tolerance, an inquiry into the source of a contaminant be made to determine whether human activity, perhaps generations earlier, may have set in motion events leading to the contamination.

The cited language in the committee report focused on the fact that naturally occurring poisons were being covered by the statue for the first time. Consequently, the casual reference to substances "added by man" is of limited significance, as it refers to an unchanged provision of the statute. Moreover, the reference to "added" substances as being those "introduced by artifice" connotes a concept different from contamination as a result of human activity.

6. One comment asserted that the few judicial decisions that have interpreted the statutory words "added" and "not * * * added" in the act do not support the definition established in the regulation. The comment claimed that "United States v. 1200 Cans, Pasteurized Whole Eggs," 393 F. Supp. 131 (N.D. Ga. 1972), was of limited precedential value because of parties stipulated that *Salmonella* in frozen eggs in an added poisonous or deleterious substance. Morever, the comment argued, *Salmonella* is not, like trace elements of natural origin in living organisms, a natural constituent of the host food, possessing potentially nutritional or other valuable properties at low levels and toxic properties at higher levels. The comment asserted that the case "United States v. 1,600,800 Pounds of White Corn," Civil No. T-4173 (D. Kan., Dec. 18, 1970), was distinguishable because the court found that there is no minimum or base line level of aflatoxin commonly found in foods. The comment argued that the Commissioner has ignored "United States v. 1232 Cases of American Beauty Brand Oysters," 43 F. Supp. 744 (W.D. Mo. 1942), which squarely held that shell fragments in cans of oysters are not "added" substances under section 402(a)(1) of the act (21 U.S.C. 342(a)(1)).

The Commissioner advises that since publication of the proposed regulation, another court has interpreted the meaning of the term "added," a decision that supports the

Commissioner's position. In the "United States v. An Article of Food Consisting of Cartons of Swordfish," 395 F. Supp. 1184 (S.D.N.Y., 1975), the court stated:

> The government also contends that mercury in swordfish is an added substance within the meaning of 21 U.S.C. § 342(a)(1) * * *. According to the government, the test for determining whether a substance is added is whether it occurs naturally in the food * * *. We agree with the government's position on the point. We find unpersuasive claimant's argument that mercury could not be an added substance because it has been found in fish for centuries. Assuming this to be so, it adds nothing to the question of whether mercury is naturally produced by fish and thus whether it is an added substance within the meaning of the statute.

That *Salmonella* is entirely foreign to frozen eggs and aflatoxin entirely foreign to white corn do not diminish the precedential value of the decisions cited with respect to contaminants identical to naturally occurring components of an organism. It is wholly consistent with the principle of the decisions that any amount of a substance above that naturally occurring is "added" within the meaning of the act. This is the interpretation codified in proposed § 122.3(d), now § 109.3(d).

The Commissioner also believes that the case "United States v. 1232 Cases of American Beauty Brand Oysters" supports the regulations. The court in that case held that shell fragments were not "added" within the meaning of the act because they were, like fish bones, inherent in the food. The case supports the thrust of § 109.3(d) which is that the test of whether a substance is "added" is whether it is intrinsically part of the food.

7. One comment stated that living organisms contain a variety of naturally occurring trace elements whose precise biological role is unknown but whose presence at low levels may be essential. The comment contended that the definitions in the proposed regulation would expand the class of "added" poisonous or deleterious substances to encompass trace elements, such as heavy metals, absorbed by animal organisms from their natural environment.

The Commissioner advises that the distinction drawn in the act, and in the regulations, between "added" and naturally occurring poisonous or deleterious substances is between substances that are inherent and those that are not. If a trace element, such as a heavy metal, is essential to the biological function of an animal, then it is inherent to that animal and it is not to be regulated as an "added" substance, unless it has been increased above the natural level by environmental contamination. If a substance is absorbed from a contaminated environment, in greater than normal amounts, it is not appropriate to regard it as naturally occurring, but to regard it as a contaminant and to take any appropriate action necessary to protect the public health. Contrary to the comment, which argues that this distinction is illogical, the Commissioner finds irrational the belief that the act of biological absorption somehow renders a contaminant "natural". Nothing in the act, or in sound science, suggests that a contaminating substance should be treated specially because it is absorbed by a living organism, or because an organism naturally contains a trace amount of the same substance. The Commissioner's position was implicitly approved in the instance of fish absorbing DDT from the water by the court in "United States v. Ewig Bros. Co.", 502 F.2d 715 (7th Cir. 1974).

8. Comments stated that numerous scientific studies have demonstrated that the level of mercury in ocean fish has remained historically constant and that mercury in

marine fish is not primarily a result of manmade pollution but is of natural origin. The comment cited studies indicating that the mercury content of 90-year-old fish, museum specimens of fish caught between 25 and 93 years ago, and various prehistoric fish are of the same order of magnitude as the mercury content of living fish of the same species. The comments argued that since the level of mercury content of the fish has not changed over time, it should not be regarded as an "added" substance but rather as naturally occurring.

The Commissioner believes that the act does not contemplate treating a contaminant differently because it has persisted in the environment for a long time. If the comment's interpretation were correct, the validity of a tolerance for a persistent contaminant would eventually be placed in doubt on the ground that the passage of time has transformed the substance from "added" to naturally occurring even though the levels occurring pose the same risks to human health. Nothing in the act supports such a result. Moreover, the comment's position was specifically considered and rejected by the court in "United States v. An Article of Food Consisting of Cartons of Swordfish", discussed above.

9. One comment questioned whether, if a very substantial portion of a commodity contains, despite all efforts, some level of a mycotoxin, that mycotoxin is an "added" substance. The comment noted that "added" was defined in the regulations as encompassing all ingredients that are not inherent parts of a food, and stated that, under the conditions identified, it would seem that mycotoxins are not necessarily "added" substances. The comment stated that certain manmade substances such as pesticides have become a component of the environment and, like certain natural substances such as mycotoxins widely occurring in nature, would not seem always to be "added" substances within the meaning of the act.

This comment points up the problem of looking only to the current state of the environment to determine whether a substance in food is "added." Certain pesticides have become ubiquitous environmental contaminants and are found in nearly all food. Nevertheless, it is clear that such pesticides are not intrinsic parts of food and should not be regarded as such. The act does not contemplate that serious contamination should be subject to lesser controls than minor contamination, which would be the result if ubiquitous contaminants were "natural" while other, less universal contaminants were regarded as "added." The Commissioner therefore concludes that under the act the test for determining whether a substance is "added" or natural is whether it is necessarily an inherent part of food, in which case it is natural. Otherwise it is "added" under the law. Thus, in the example of mycotoxins suggested by comment, the inquiry is not whether all lots of the commodity contain mycotoxin contamination, but whether the mycotoxin is inherently part of the food. This approach will permit adequate control over contaminants, from whatever source, and is the approach contemplated by section 406 of the act.

10. One comment requested clarification of FDA's policy concerning "environmental contamination." The comment gave as an example that corn grown in South Dakota averaged 0.40 part per million (ppm) selenium, while corn grown in Indiana averages 0.04 ppm selenium. The comment stated that these differences are presumably due to differences in selenium content of the soil. The comment questioned whether the differences between 0.04 and 0.40 ppm is "added" selenium. The comment interpreted the regulations, in referring to environmental contamination, as treating increased levels of substances to be "added" only when the increase is caused by man.

The Commissioner does not agree with the comment's interpretation. A substance is "added" within the meaning of the statute when it is increased to abnormal levels through intervening circumstances; these need not involve human intervention, but could involve merely the kinds of geological processes that raise the concentration of a toxic trace element to unusually high concentration in a particular locality. If food may pose a risk to health because of the abnormally high mineral content of the soil in which it is grown, it is appropriate under the act that the Commissioner take action to protect the public health. To repeat, contamination of concern is in no way limited to that which can be attributed to man.

11. One comment stated that the reason we have poisons in our food is due mainly to governmental agencies that allow pesticides to enter the food chain. The comment stated that if farmers knew that the contaminated foods could not be marketed, they would use more natural methods to prevent crop destruction.

The Commissioner advises that the use of pesticides is regulated by the U.S. Environmental Protection Agency (EPA), which establishes conditions for their safe use and tolerance levels for residues resulting from such use. Nothing in these regulations would permit the sale of food that was contaminated beyond the established tolerance or action level or was contaminated through unlawful use of a pesticide or any other added substance except in the rare instance in which such contamination is of such magnitude that destruction of the food would constitute a substantial adverse impact on the national food supply and then only if the food itself is safe for consumption.

12. One comment requested clarification of the meaning of a "poisonous or deleterious substance." The comment stated that a substance may be beneficial or even essential at one level, and yet poisonous or deleterious at a higher level.

The language "poisonous or deleterious substance" appears in section 402(a)(2) of the act (21 U.S.C. 342(a)(2)), and it is not further defined. The Commissioner concludes that clarification of the term is not necessary for purposes of these regulations. The issue in an administrative proceeding to establish a tolerance or action level is the level necessary to protect the public health. Accordingly, it is unnecessary to specify in the abstract what constitutes a "poisonous or deleterious substance."

13. One comment stated that proposed § 122.6(b)(2) (now § 109.6(b)(2)), which provides that a tolerance will be established at a level "sufficient for the protection of the public health," fails to define what constitutes "sufficient" in terms of a margin of safety. The comment stated that if FDA plans to allow such margins, the regulations should so specify with particularity.

The Commissioner advises that it is not possible to specify in advance the margin of safety that will be used for any given contaminant. Particularly in the case of action levels, available data on safety may be so limited that it will be unclear what margin of safety is being provided. Nevertheless, it may be appropriate to establish an action level based on the little data that are available. Also, as was the case, for example, in the proposed action level for mercury in fish and shellfish (December 6, 1974, 39 FR 42738), the margin of safety may vary greatly depending upon how much of the food a particular individual consumes. So far as possible, a proposal to establish a tolerance and the supporting material on file with the Hearing Clerk in the case of an action level will provide information from which it may be concluded what margin of safety is being established. Comments could then address the question whether the margin is sufficient under the circumstances.

14. One comment questioned the language of proposed § 122.4(b) (now § 109.4(b)(1)) which states that an action level "may prohibit any detectable amount of the substance in food." The comment was concerned that nothing more was said about methodology in the regulations. The comment questioned whether the existence of an action level would be dependent upon a specifically approved method of detection.

The Commissioner advises that in establishing an action level or tolerance he will specify the method of detection that is to be used to ensure compliance with the tolerance or action level.

15. One comment referred to the language in proposed § 122.4(a) (now § 109.4(a)) that a tolerance may be established at the level of zero. The comment stated that "zero" depends upon the sensitivity of the method, and suggested that it would be more accurate to state that a tolerance may be established at "no detectable amount of the substance in the food."

The Commissioner agrees with the comment and has revised the regulation accordingly. The Commissioner advises that when a tolerance is established at the level of zero, a method of analysis will always be specified in the regulation establishing the tolerance.

16. One comment opposed proposed § 122.7(a) (now § 109.7(a)), which states that tolerances and action levels will be established at levels "based on the unavoidability of the poisonous or deleterious substance concerned." The comment asserted that section 406 of the act does not permit establishing a tolerance based on a substance's degree of unavoidability, but must be confined to toxicological aspects. The comment asserted that a potentially offending substance need not be eliminated from a class of foods where it is present at completely safe levels simply because it can be eliminated. The comment asserted that

FDA has a duty to permit theoretically avoidable but nevertheless safe levels of poisonous or deleterious substances.

The Commissioner advises that the standard of unavoidability established by section 406 of the act is whether the substance can be avoided by good manufacturing practice. If a substance can be avoided by good manufacturing practice, it is deemed by section 402(a)(2)(A) of the act to be unlawful at any level. If a substance cannot be avoided, the Commissioner is expressly directed by section 406 of the act to "take into account the extent to which the use of such substance * * * cannot be avoided" in the production of food. Therefore, the agency must consider the degree of unavoidability of a substance and not simply toxicological aspects.

17. Comments contended that the section on unavoidability (§ 122.7, now § 109.7) does not adequately define the term. The comments stated that adulteration is not unavoidable simply because all purveyors of a food product produce a similarly adulterated item. They stated that customary practice of the industry is not the measure of duty or due care, and that FDA should make clear in this section that objective capability, and not industry practice, defines unavoidability.

As noted above, the act defines an unavoidable substance as one that cannot be avoided by good manufacturing practice. The Commissioner agrees that an industry's customary practice does not necessarily constitute good manufacturing practice. Section 122.7 (now § 109.7) states that the manufacturer of food must at all times utilize quality control procedures which will reduce contamination to the lowest level currently feasible. However, the specific criteria for determining good manufacturing practice will vary. An attempt to define

particular circumstances in which an industry's practice does not constitute good manufacturing practice would be beyond the scope of these regulations.

18. Comments objected to the definition of "food" in proposed § 122.3(e) (now § 109.3(e)) because it is different from the definition of "food" in section 201(f) of the act. One comment asserted that indirect food additives, that is, substances migrating to food from food-contact articles, are not foods within the meaning of the definition of section 201(f).

The Commissioner advises that all food additives are "foods" under the law. Moreover, all substances migrating from food-contact surfaces are "foods" within the meaning of the act. This position has been upheld by the courts in *United States* v. *Articles of Food,* 370 F. Supp. 371 (E.D. Mich. 1974), and in *Natick Paperboard Corp.* v. *Weinberger,* 389 F. Supp. 794 (D. Mass. 1975), aff'd, 525 F.2d 1103 (1st Cir. 1975). Thus, the regulation simply clarifies the scope of the act for the benefit of the public and regulated industry. Under Part 109 a tolerance or action level may be established for an unavoidable contaminant of a packaging material or other food-contact article. For example, the existing (stayed) tolerance for polychlorinated biphenyls establishes a tolerance for their presence in paper packaging materials (21 CFR 109.30(a)(9), formerly 21 CFR 122.10(a)(9)).

19. One comment suggested that there should be different definitions for "food" and "feed" because in many instances the poisonous or deleterious substance in question should be treated differently depending on whether it is intended for human or animal consumption.

The Commissioner agrees that different tolerances or action levels may be established for human and animal food. These differences will be reflected in the individual tolerances or action levels established, where appropriate.

Changing the definition of "food" would not facilitate this approach, however, nor is it necessary to its implementation.

20. One comment stated that it is unrealistic to establish tolerances or action levels for contaminants that are equally applicable to human food and animal feeds. The comment stated that animal feeds and human food should be considered separately throughout the regulations.

As noted, the Commissioner agrees that it will often be appropriate to establish different tolerances or action levels for human food and animal feeds.

21. The proposed regulations provided for the establishment of action levels through informal (i.e., notice and comment) rule making. The Commissioner has reconsidered this aspect of the proposal, and for the reasons discussed below, concludes that an alternative procedure is preferable. The approach adopted will conserve limited FDA resources while preserving the opportunity for the public to comment upon any action level set and the scientific bases for the decision.

In the preamble to the proposal, the Commissioner stated that action levels, as opposed to tolerances under section 406 of the act, are appropriate in dynamic circumstances. Thus, an action level is appropriate if industrial practices are improving so quickly that the extent to which a substance is avoidable changes significantly from year to year, or if toxicological data are scanty or conflicting but additional data are being developed. The procedures required by section 406 of the act, including a public hearing and the requirement of substantial evidence to support a tolerance, contemplate ample evidence, and a relatively stable situation, in which any tolerance promulgated will be appropriate for a relatively long period of time.

There is an inherent conflict between the dynamic circumstances in which an action level is appropriate and the use of rule making to set such a level. Although the time required to set an action level through informal rule making is less than that required for a tolerance under section 406 of the act, establishment of action levels through informal rule making would still involve a substantial amount of time and agency resources. Because of the time required to promulgate an action level and the dynamic circumstances in which action levels are used, the possibility exists that an action level will be outdated soon after it is promulgated, in which case the process would have to begin anew. The potential for wasteful expenditure of agency resources has persuaded the Commissioner that a simplified procedure for adopting action levels should be used.

In so concluding, however, the Commissioner is mindful of the need to provide for public access to, and review of, the data on which FDA relies in setting an action level and for an opportunity to comment upon the level set. The bases and rationale for action levels cannot be shielded from the public if the agency's decisions are to be credible. In evaluating various alternative procedures for setting action levels, the Commissioner has given great weight to the extent to which specific alternatives would satisfy this need.

The Commissioner recognizes that the approach described below and adopted in § 109.4(b)(2) of the regulations may prove not wholly satisfactory. The Commissioner is committed to reviewing the procedure periodically and to proposing revisions if they appear to be appropriate.

Under § 109.4(b) of the regulations, when the agency sets an action level for a specific poisonous and deleterious substance, a notice will be published in the FEDERAL REGISTER announcing that fact. Before the notice is pub-

lished, the FDA will place on file with the Hearing Clerk all pertinent data and information regarding the substance, including FDA memoranda analyzing those data and discussing the rationale for the level that has been chosen. The notice will explicitly call attention to the material placed on file with the Hearing Clerk. Additionally, the notice will invite and specify a time for public comments on the level. FDA will review any comments received and, as part of the continuing process of reviewing action levels, modify any level if the comments warrant that action. Any interested person may petition the FDA to set a different action level under the procedures set forth in 21 CFR Part 10 (Subpart A of Part 2, prior to recodification published in the FEDERAL REGISTER of March 22, 1977 (42 FR 15553)).

On occasion it may be necessary to set an action level to respond to any "emergency" situation. In such a case, a memorandum will be placed on file with the Hearing Clerk stating that an action level has been set. As soon as possible thereafter, a notice will be published in the FEDERAL REGISTER to the same effect.

Because of the dynamic circumstances in which action levels are used, it will frequently be necessary to revise a particular action level before a notice can be published in the FEDERAL REGISTER. A notice will be published as soon as possible whenever an action level is changed. The Commissioner anticipates that a notice will be published in the near future setting forth all existing action levels for poisonous and deleterious substances.

22. One comment questioned whether there is any authority or justification for section 406 tolerances for food additives that may be regulated under section 409 of the act. The comment asserted that food additives are entirely avoidable, as distinquished from the unavoidable contaminants with which section 406 of the act deals.

The Commissioner agrees in part with the comment. Tolerances under section 406 of the act (and action levels) should not be established in Part 109 for intentionally added food ingredients or for components of food-contact articles that serve a functional purpose in the food-contact article. Tolerances under section 406 of the act and action levels may be established only for contaminants of food or food-contact articles, such as the tolerances established for polychlorinated biphenyls unavoidably present in several classes of food and in paper-packaging materials (21 CFR 122.100, now 21 CFR 109.30). Such contaminants may include substances that are "food additives" within the meaning of the act if the substances are unavoidable in a particular food; this conclusion was fully discussed in the preamble to the proposed regulations.

The Food and Drug Administration may have occasion to establish an action level for an intentionally used food ingredient or for a functional component of a food-contact article. If questions arise about the safety of a substance that has long been used in food on the assumption that the substance was generally recognized as safe, it might be appropriate to issue an interim food additive regulation under § 180.1 (21 CFR 180.1) (formerly 21 CFR 121.4000) to permit the continued safe use of the substance while the questions are being resolved. However, it might also be appropriate to restrict use of the substance while the interim food additive regulation is being made final. In such a case an action level would be announced to establish the level at which FDA would take action against the substance under section 402(a)(2)(C) of the Act. An interim food additive regulation would be proposed as soon thereafter as practicable. The Commissioner has added a new paragraph (f) to § 180.1 to set forth the conditions under which such an action level may be considered. A similar paragraph has been added to

§ 181.1 (21 CFR 181.1) (formerly 21 CFR 121.2000) to identify the conditions under which an action level may be established for a prior-sanctioned substance. No action level would be established for an approved food additive, however; the procedure for changing the permitted conditions of use of an approved food additive is that prescribed in section 409 of the act.

The first action levels established for functional componets of food-contact articles are to control lead and cadmium migration from pottery and enamelware, lead migration from silver-plated hollowware, and lead migration from cans containing evaporated milk and skim milk to their contents. These action levels currently exist and will continue to be used.

23. Comments recommended that the circumstances described in § 122.8 (now § 109.8) under which an unlawfully contaminated food could be permitted to be marketed should not be as stringent as those circumstances in which there would be a "substantial adverse impact on the national food supply." The comments argued that it is conceivable that destruction of a single contaminated product could ever have such an impact and suggested that an exception be permitted whenever destruction of the food involved "would cause a needless waste of food and thus an unwarranted economic loss to the consuming public." Another comment suggested that the criterion should be whether the destruction or diversion of the food involved would "contribute to an adverse impact on the national food or feed supply."

The Commisioner concludes that it is not appropriate to sanction the essentially routine marketing of unlawfully contaminated food as was suggested by these comments. The act permits establishing tolerances and action levels for food that has been unavoidably contaminated. If, however, the food was at some stage of its production unlawfully (i.e., avoidably) contaminated, then the act

contemplates that such food shall ordinarily not be marketed. Consquently, the Commissioner concludes that such food should be permitted to be marketed only in the most extraordinary circumstances.

The proper functioning of the agency's regulatory program requires that unlawfully contaminated food ordinarily be destroyed to make unlawful action unprofitable. The fact that the present owner of the food may not have been responsible for the avoidable contamination is not a convincing reason for departing from this policy. To create an exception for persons who unknowingly purchase contaminated foods would permit persons engaged in illegal conduct to profit from their illegal actions. If unlawfully contaminated food were permitted to be sold, then its owner would have no cause of action for damages in a civil action against the person responsible for the contamination. The only action that could be taken against the person responsible for the contamination would be criminal prosecution, where the government is required to prove guilt beyond a reasonable doubt, and where the penalties imposed are likely to be small in relationship to the value of the goods. Consequently, the Commissioner concludes that it is necessary for proper enforcement of the act that unlawfully contaminated food ordinarily be seized and destroyed, notwithstanding the fact that it may be at the time of such destruction in the hands of an innocent party, and notwithstanding the fact it may on occasion be safe for consumption.

24. One comment sought clarification of § 109.8 which refers to "a substantial adverse impact on the national food supply" and stated that carload or warehouse lots of adulterated foods should not fall into this category. Another questioned whether the unavailability of one variety of fruit or vegetable would result in a "substantial adverse impact." Other examples posed included whether

a few pennies per week inflation in the price of food would constitute such an adverse impact and whether the bankruptcy of a major food company as a result of destruction or diversion of certain food would constitute a substantial adverse impact on the national food supply.

The Commissioner agrees that the loss of carload or warehouse lots of adulterated food would almost never have a substantial adverse impact on the national food supply. It would not be appopriate to examine and pass on all possible circumstances at this time, however. In accordance with § 109.8(a)(2), whenever possible an exemption will be issued only after opportunity for public comment.

25. One comment stated that, if unlawfully contaminated food is permitted to be sold in accordance with § 109.8, FDA should investigate the reason for the contamination and not exclude civil or criminal action against responsible individuals even though the food was sold.

The Commissioner agrees with this comment. Granting an exemption does not exempt from liability the person who unlawfully contaminated the food. The Food and Drug Administration would investigate and initiate appropriate regulatory action against persons responsible for unlawfully contaminated food, even if the food were permitted to be sold.

26. Comments objected to the provision in § 109.6(d) that applies when the effectiveness of a tolerance is stayed pursuant to section 701(e)(2) of the act (21 U.S.C. 371(e)(2)) by the filing of an objection. Under that section, the order establishing the tolerance is deemed to be an order establishing an action level until final action is taken upon the objection. Comments argued that if a hearing is requested, the reasonableness of the tolerance would be in doubt and that, therefore, its enforcement as an action level would not be justified. One comment suggested that a tolerance became an action level only in cases where a hazard to health is involved.

The Commissioner notes that if the substance that is the subject of the tolerance is a food additive, it is unlawful at a detectable level, under section 402(a)(2)(C) of the act (21 U.S.C. 342 (a)(2)(C)). Thus, if a tolerance is stayed by an objection, the presence of the substance is unlawful at any level, and regulatory action may be taken; an action level is appropriate to determine the level at which action should be taken. This approach was approved by the Court of Appeals in "Natick Paperboard Corp. v. Weinberger," cited above.

If the substance is not a food additive, but is an unavoidable "added" poisonous or deleterious substance, then action may be taken pursuant to section 402(a)(1) of the act, which remains applicable to a particular substance until a tolerance is in effect. Thus, for substances that are not food additives, a tolerance indicates the level at which the Commissioner will take action against a substance on the ground that the level may be injurious to health. The establishment of a tolerance does not make unlawful what would otherwise be lawful; it may, however, make lawful what would otherwise be unlawful.

The Commissioner rejects the suggestion that a tolerance stayed by an objection should become an action level only in cases where a hazard to health is involved. By hypothesis, in the case of poisonous or deleterious substances a potential hazard to health always exists, and that is the basis upon which action levels and tolerances are established.

27. One comment asserted that FDA may not avoid the procedures of section 406 of the act by establishing an action level. The comment stated that where Congress has specified with particularity the hearing procedures by which a certain administrative action may be taken, an agency is without authority to depart from the congressionally mandated process. The comment asserted that FDA is obligated to elect one of two courses: it must either disclaim any intent to attach the force of law to its action

levels, or it must adopt those action levels as tolerances under section 406 of the act and in accord with the procedures specified in section 701(e) of the act.

The Commissioner disagrees. As to those substances that would be illegal at any level in the absence of an action level, e.g., because they are food additives, the courts have upheld FDA's authority to issue action levels. Those cases were cited in the preamble to the proposed regulation. As to other substances, the act clearly contemplates that the Government may proceed against a contaminated food under section 402(a)(1) of the act when no tolerance is effective. Furthermore, in light of the procedure adopted for establishing action levels in the regulations, this point, for the present at least, is moot.

28. One comment included data and arguments concerning the tolerance for polychlorinated biphenyls.

The Commissioner notes that the tolerances for polychlorinated biphenyls were not proposed in the FEDERAL REGISTER of December 6, 1974, but were simply reprinted because the section number is being changed.

29. One comment stated that the republication of the tolerance for polychlorinated biphenyls in paper-packaging materials should state that the regulation is stayed.

The Commissioner agrees and has added an appropriate note.

30. One comment offered an interpretation of the proviso in section 402(a)(2)(C) of the act, which provides that a pesticide chemical present in a processed food is lawful if the residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity. The comment interpreted the term "ready to eat" as permitting a processed food to contain a higher concentration of pesticide than is permitted for the raw agricultral commodity if the food is "disbursed" in other food when consumed in a manner such that the

pesticide level of the mixture is below the tolerance. As an example, the comment cited dehydrated peppers, which contain pesticide residues greater than the tolerance for raw peppers because of the dehydration; the comment contended that the dehydration pepper was not "ready to eat" until it had been incorporated into a finished food and that the tolerance is properly applied to the entire finished food into which it was incorporated.

The Commissioner disagrees with the interpretation of the act offered by the comment. The term "ready to eat" does not permit compliance with a tolerance to be determined after the food has been mixed with other food; the term applies when a food is to be modified before use, e.g., by hydration.

One of the principal purposes for which a tolerance is established by regulation is to provide a readily ascertainable standard by which FDA and affected persons can determine whether a particular lot of food conforms to the requirements of the law. Under the interpretation suggested by the comment, there would be no definite standard to determine whether a particular lot of dehydrated peppers complies with the law. Instead, its legality would turn on uncertain subsequent events involving the manner in which the food was to be used. By contrast, foods that are not ready to eat because they must be modified in a particular way may be so modified prior to analysis, and compliance may thus be determined with certainty. In the event that processing increases the concentration of a pesticide, the act permits a tolerance to be established under section 409 of the act; this procedure permits a clear, enforceable limit and is the procedure to be followed.

31. The Commissioner has revised proposed § 109.4(b) to delete the reference to section 402(a)(1) of the act. This reference was inconsistent with § 109.6(c), which establishes the standards for an action level. The Commis-

sioner has also revised proposed § 109.6(d), which refers to the statutory authority for issuing tolerances and action levels, by explicitly stating the pertinent sections of the act.

32. The Commissioner has revised proposed § 109.6(a), to clarify the relationship of FDA and EPA in establishing tolerances and action levels for added poisonous and deleterious substances that are also pesticide chemicals. The regulations that EPA issues under sections 406, 408, and 409 of the act will establish tolerances; FDA will implement action levels under the criteria of these procedural regulations. Upon FDA's request, EPA will recommend an action level based on the criteria set forth in these procedural regulations.

33. The Commissioner advises that the prohibition in the regulations against marketing unlawfully contaminated food is not intended to change the agency's current policy permitting the diversion of contaminated human food into use as animal feed when such diversion would pose no significant risks to human or animal health. Proposed regulations will be published in the FEDERAL REGISTER to formally establish the permissible conditions for such diversion.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 306, 402(a), 406, 408, 409, 701(a), 52 Stat. 1045-1046 as amended, 1049 as amended, 1055, 68 Stat. 511-518 as amended; 72 Stat. 1785-1788 as amended (21 U.S.C. 336, 342(a), 346, 346a, 348, 371(a))) and under authority delegated to him (21 CFR 5.1), Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

1. By revising Part 109 to read as follows:

PART 109—UNAVOIDABLE CONTAMINANTS IN FOOD FOR HUMAN CONSUMPTION AND FOOD-PACKAGING MATERIAL

Subpart A—General Provisions

Sec.

109.3 Definitions and interpretations.
109.4 Establishment of regulations.

109.5 Petitions.
109.6 Added poisonous or deleterious substances.
109.7 Unavoidability.
109.8 Exemptions.
109.15 Use of polychlorinated biphenyls (PCB's) in establishments manufacturing food-packaging materials.

Subpart B—Tolerances for Unavoidable Poisonous or Deleterious Substances

109.30 Temporary tolerances for polychlorinated biphenyls (PCB's).

Subpart C—Naturally Occurring Poisonous or Deleterious Substances—[Reserved]

AUTHORITY: Secs. 306, 402(a), 406, 408, 409, 701, 52 Stat. 1045-1046 as amended, 1049 as amended, 1055-1056 as amended, 68 Stat. 511-518 as amended, 72 Stat. 1785-1788 as amended (21 U.S.C. 336, 342(a), 346, 346a, 348, 371).

Subpart A—General Provisions

§ 109.3 Definitions and interpretations.

(a) "Act" means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms contained in section 201 of the act are applicable to such terms when used in this part unless modified in this section.

(c) A "naturally occurring poisonous or deleterious substance" is a poisonous or deleterious substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other contamination.

(d) An "added poisonous or deleterious substance" is a poisonous or deleterious substance that is not a naturally occurring poisonous or deleterious substance. When a naturally occurring poisonous or deleterious substance is increased to abnormal levels through mishandling or other intervening acts, it is an added poisonous or deleterious substance to the extent of such increase.

(e) "Food" includes human food and substances migrating to food from food contact articles.

§ 109.4 Establishment of regulations.

(a) When appropriate under the criteria of § 109.6, a tolerance for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in Subpart B of this part under the provisions of section 406 of the act. A tolerance may prohibit any detectable amount of the substance in food.

(b)(1) When appropriate under the criteria of § 109.6, an action level for an added poisonous or deleterious substance, which may be a food additive, may be established to define the level of contamination at which a food will be deemed to be adulterated. An action level may prohibit any detectable amount of the substance in food.

(2) Whenever an action level is established, a notice shall be published in the FEDERAL REGISTER as soon as practicable thereafter. The notice shall call attention to the material supporting the action level which shall be on file with the Hearing Clerk before the notice is published. The notice shall invite public comment on the action level. Regulatory action may be taken at any time after an action level is established, and need not await publication of the notice. An action level may be changed at any time if the protection of the public health so requires. A notice shall be published in the FEDERAL REGISTER as soon as practicable after an action level is changed.

(c) A regulation may be established in Subpart C of this part to identify a food containing a naturally occurring poisonous or deleterious substance which will be deemed to be adulterated under section 402(a)(1) of the act. These regulations do not constitute a complete list of such foods.

§ 109.5 Petitions.

The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may issue a proposal to establish, revoke, or amend a regulation under this part. Any such petition shall include an adequate factual basis to support the petition, shall be in the form set forth in § 10.65 of this chapter, and will be published in the FEDERAL REGISTER for comment if it contains reasonable grounds for the proposed regulation.

§ 109.6 Added poisonous or deleterious substances.

(a) Use of an added poisonous or deleterious substance, other than a pesticide chemical, that is also a food additive will be controlled by a regulation issued under section 409 of the act when possible. When such a use cannot be approved under the criteria of section 409 of the act, or when the added poisonous or deleterious substance is not a food additive, a tolerance or action level may be established pursuant to the criteria established in paragraphs (b) and (c) of this section. Residues resulting from the use of an added poisonous or deleterious substance that is also a pesticide chemical will ordinarily be controlled by a tolerance established in a regulation issued under section 406, 408, or 409 by the U.S. Evironmental Protection Agency (EPA). When such a regulation has not been issued, an action level for added poisonous or deleterious substance that is also a pesticide chemical may be established by the Food and Drug Adminstration. The

Food and Drug Administration will request EPA to recommend such an action level pursuant to the criteria established in paragraph (c) of this section.

(b) A tolerance for an added poisonous or deleterious substance in any food may be established when the following criteria are met:

(1) The substance cannot be avoided by good manufacturing practice.

(2) The tolerance established is sufficient for the protection of the public health, taking into account the extent to which the presence of the substance cannot be avoided and the other ways in which the consumer may be affected by the same or related poisonous or deleterious substances.

(3) No technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance established. Examples of changes that might affect the appropriateness of the tolerance include anticipated improvements in good manufacturing practice that would change the extent to which use of the substance is unavoidable and anticipated studies expected to provide significant new toxicological or use data.

(c) An action level for an added poisonous or deleterious substance in any food may be established when the criteria in paragraph (b) of this section are met, except that technological or other changes that might affect the appropriateness of the tolerance are foreseeable in the near future. An action level shall cease to be enforced and shall be revoked when a tolerance for the same substance and use has become effective.

(d) Tolerances will be established under the authority appropriate for action levels (sections 306, 402(a), and 701(a) of the act, together with section 408 or 409 if appropriate) as well as under authority appropriate for tolerances (sections 406 and 701 of the act). In the event the effectiveness of a tolerance is stayed pursuant to section 701(e)(2) of the act by the filing of an objection, the

order establishing the tolerance shall be deemed to be an order establishing an action level until final action is taken upon such objection.

§ 109.7 Unavoidability.

(a) Tolerances and action levels in this part are established at levels based on the unavoidability of the poisonous or deleterious substance concerned and do not establish a permissible level of contamination where it is avoidable.

(b) Compliance with tolerances and action levels does not excuse failure to observe either the requirement in section 402(a) (4) of the act that food may not be prepared, packed, or held under insanitary conditions or the other requirements in this chapter that food manufacturers must observe current good manufacturing practices. Evidence obtained through factory inspection or otherwise indicating such a violation renders the food unlawful, even though the amounts of poisonous or deleterious substances are lower than the currently established tolerances or action levels. The manufacturer of food must at all times utilize quality control procedures which will reduce contamination to the lowest level currently feasible.

§ 109.8 Exceptions.

(a) The Commissioner may exempt from the regulatory action and permit the marketing of any food that is unlawfully contaminated with a poisonous or deleterious substance if:

(1) He determines (i) based upon all available scientific evidence, that the food is safe for consumption and (ii) that destruction or diversion of the food involved would result in a substantial adverse impact on the national food supply.

(2) Such determination is published as a notice in the FEDERAL REGISTER and public comment shall be invited on

the determination. The notice shall call attention to the material supporting the determination, which shall be on file with the Hearing Clerk before the notice is published.

(3) The determination identifies the level of contamination allowed by the exemption, and the food to which it applies, e.g., the specific growing area or other identifying information. The exemption shall not apply to any other food produced in any other area or at any other time. Contaminated food not subject to the exemption will remain subject to regulatory action.

(b) Any person responsible for contamination of the food involved, or shipment of any such food in interstate commerce prior to the issuance of an exemption pursuant to this section, shall remain subject to regulatory action pursuant to sections 302 (injunction proceedings) and 303 (penalties) of the act.

(c) In the case of a poisonous or deleterious substance which is a pesticide chemical, the level of contamination allowed by the exemption shall, upon request of the Food and Drug Administration, be specified by the Environmental Protection Agency pursuant to paragraph (a) (1) (i) of this section and promugated by the Commissioner. No exemption for a pesticide chemical shall be promulgated without the concurrence of the Environmental Protection Agency.

§ 109.15 Use of polychlorinated biphenyls (PCB's) in establishments manufacturing food-packaging materials.

(a) Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Aroclor (United States); Phenoclor (France); Colphen (Germany); and Kanaclor (Japan). PCB's are highly stable, heat resistant, and nonflammable chemicals. Industrial uses of PCB's include, or did include in the past, their use as electrical transformer and capacitor fluids, heat transfer fluids, hydraulic fluids, and plasticizers, and in formulations of

lubricants, coatings, and inks. Their unique physical and chemical properties and widespread, uncontrolled industrial applications have caused PCB's to be a persistent and ubiquitous contamination in the environment, causing the contamination of certain foods. In addition, incidents have occurred in which PCB's have directly contaminated animal feed as a result of industrial accidents (leakage or spillage of PCB fluids from plant equipment). These accidents in turn caused the contamination of food products intended for human consumption (meat, milk, and eggs). Investigations by the Food and Drug Adiministration have revealed that a significant percentage of paper food-packaging material contains PCB's which can migrate to the packaged food. The origin of PCB's in such material is not fully understood. Reclaimed fibers containing carbonless copy paper (contains 3 to 5 percent PCB's) have been identified as a primary source of PCB's in paper products. Some virgin paper products have also been found to contain PCB's. The source of which is generally attributed to direct contamination from industrial accidents from the use of PCB-containing equipment and machinery in food-packaging manufacturing establishments. Since PCB's are toxic chemicals, the PCB contamination of food-packaging materials as a result of industrial accidents, which cause the PCB contamination of food, represents a hazard to public health. It is therefore necessary to place certain restrictions on the industrial uses of PCB's in establishments manufacturing food-packing materials.

(b) The following special provisions are necessary to preclude the accidental PCB contamination of food-packaging materials:

(1) New equipment or machinery for manufacturing food-packaging materials shall not contain or use PCB's.

(2) On or before September 4, 1973, the management of establishments manufacturing food-packaging materials shall:

(i) Have the heat exchange fluid used in existing equipment for manufacturing food-packaging materials sampled and tested to determine whether it contains PCB's or verify the absence of PCB's in such formulations by other appropriate means. On or before September 4, 1973, any such fluid formulated with PCB's must to the fullest extent possible commensurate with current good manufacturing practices be replaced with a heat exchange fluid that does not contain PCB's.

(ii) Eliminate to the fullest extent possible commensurate with current good manufacturing practices from the establishment any other PCB-containing equipment, machinery and materials wherever there is a reasonable expectation that such articles could cause food-packaging materials to become contaminated with PCB's either as a result of normal use or as a result of accident, breakage, or other mishap.

(iii) The toxicity and other characteristics of fluids selected as PCB replacements must be adequately determined so that the least potentially hazardous replacement is used. In making this determination with respect to a given fluid, consideration should be given to (*a*) its toxicity; (*b*) the maximum quantity that could be spilled onto a given quantity of food before it would be noticed, taking into account its color and odor; (*c*) possible signaling devices in the equipment to indicate a loss of fluid, etc.; and (*d*) its environmental stability and tendency to survive and be concentrated through the food chain. The judgment as to whether a replacement fluid is sufficiently nonhazardous is to made on an individual installation and operation basis.

(c) The provisions of this section do not aply to electrical transformers and condensers containing PCB's in sealed containers.

Subpart B—Tolerance for Unavoidable Poisonous or Deleterious Substances

§ 109.30 Polychlorinated Biphenyls (PCB's).

(a) Polychlorinated biphenyls (PCB's) are toxic, industrial chemicals. Because of their widespread, uncontrolled industrial applications, PCB's have become a persistent and ubiquitous contaminant in the environment. As a result, certain foods and animal feeds, principally those of animal and marine origin, contain PCB's as unavoidable, environmental contaminants. PCB's are transmitted to the food portion (meat, milk, and eggs) of food producing animals ingesting PCB contaminated animal feed. In addition, a significant percentage of paper food-packaging materials contain PCB's which may migrate to the packaged food. The source of PCB's in paper food-packaging materials is primarily of certain types of carbonless copy paper (containing 3 to 5 percent PCB's) in waste paper stocks used for manufacturing recycled paper. Therefore, temporary tolerances for residues of PCB's as unavoidable environmental or industrial contaminants are established for a sufficient period of time following the effective date of this paragraph to permit the elimination of such contaminants at the earliest practicable time. For the purposes of this paragraph, the term "polychlorinated biphenyls (PCB's)" is applicable to mixtures of chlorinated biphenyl compounds, irrespective of which mixture of PCB's is present as the residue. The temporary tolerances for residues of PCB's are as follows:

(1) 2.5 parts per million in milk (fat basis).

(2) 2.5 parts per million in manufacturing dairy products (fat basis).

(3) 5 parts per million in poultry (fat basis).

(4) 0.5 parts per million in eggs.

(5) 0.2 parts per million in finished animal feed for food-producing animals (except the following finished animal feeds: feed concentrates, feed supplements and feed premixes).

(6) 2 parts per milion in animal feed components of animal origin, including fishmeal and other by-products of marine origin, and in finished animal feed concentrates, supplements, and premixes intended for food producing animals.

(7) 5 parts per million in fish and shellfish (edible portion). The edible portion of fish excludes head, scales, viscera, and inedible bones.

(8) 0.2 parts per million in infant and junior foods.

(9) 10 parts per million in paper food-packaging material intended for or used with human food, finished animal feed and any components intended for animal feeds. The tolerance shall not apply to paper food-packaging material separated from the food therein by a functional barrier which is impermeable to migration of PCB's.

(b) A compilation entitled "Analytical Methodology for Polychlorinated Biphenyls, February 1973" for determining compliance with the tolerences established in this section is available from the Hearing Clerk, Department of Health, Education, and Welfare, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

NOTE.—At 38 FR 22794, Aug. 24, 1973, the following appeared concerning § 109.30(a)(9) (formerly 122.10(a)(9)):

* * * § 109.30(a)(9) is hereby stayed pending full review of the objections and requests for hearing. * * *

In the interim, as stated in the final order (38 FR 18098) the Food and Drug Administration will enforce the temporary tolerance level established by § 109.30(a)(9) by seizing any paper food-packaging material shipped in interstate commerce after September 4, 1973, containing higher than the specified level of PCB's as adulterated in violation of sec. 402 of the act.

Subpart C—Naturally Occurring Poisonous or Deleterious Substances [Reserved]

PART 180—FOOD ADDITIVES PERMITTED IN FOOD ON AN INTERIM BASIS OR IN CONTACT WITH FOOD PENDING ADDITIONAL STUDY

2. By adding new paragraph (f) to § 180.1 to read as follows:

§ 180.1 General.

* * * * *

(f) Where appropriate, an emergency action level may be issued for a substance subject to paragraph (a) of this section that is not an approved food additive, pending the issuance of a final interim food additive regulation. Such an action level shall be issued pursuant to sections 306 and 402(a) of the act to identify, based upon available data, a safe level of use for the substance. Such an action level shall be issued in a notice published in the FEDERAL REGISTER and shall be followed as soon as practicable by a proposed interim food additive regulation. Where the available data do not permit establishing an action level

for the safe use of a substance, use of the substance may be prohibited. The identification of a prohibited substance may be made in Part 189 of this chapter when appropriate.

PART 181 – PRIOR-SANCTIONED FOOD INGREDIENTS

3. By adding new paragraph (c) to § 181.1 to read as follows:

§ 181.1 General.

* * * * *

(c) Where appropriate, an emergency action level may be issued for a prior-sanctioned substance, pending the issuance of the final regulation in accordance with paragraph (b) of this section. Such an action level shall be issued pursuant to section 402(a) of the act to identify, based upon available data, conditions of use of the substance that may be injurious to health. Such an action level shall be issued in a notice published in the FEDERAL REGISTER and shall be followed as soon as practicable by a proposed regulation in accordance with paragraph (b) of this section. Where the available data demonstrate that the substance may be injurious at any level, use of the substance may be prohibited. The identification of a prohibited substance may be made in Part 189 of this chapter when appropriate.

PART 509 – UNAVOIDABLE CONTAMINANTS IN ANIMAL FOOD AND FOOD-PACKAGING MATERIAL

4. Part 509 is revised to read as follows:

Subpart A – General Provisions

Sec.

509.3 Definitions and interpretations.
509.4 Establishment of regulations.
509.5 Petitions.
509.6 Added poisonous or deleterious substances.
509.7 Unavoidability.
509.8 Exemptions.
509.15 Use of polychlorinated biphenyls (PCB's) in establishments manufacturing food-packaging materials.

Subpart B – Tolerances for Unavoidable Poisonous or Deleterious Substances

509.30 Temporary tolerances for polychlorinated biphenyls (PCB's).

Subpart C – Naturally Occurring Poisonous or Deleterious Substances – [Reserved]

AUTHORITY: Secs. 306, 402(a), 406, 408, 409, 701, 52 Stat. 1045-1046 as amended, 1049 as amended, 1055-1056 as amended, 68 Stat. 511-518 as amended, 72 Stat. 1785-1788 as amended (21 U.S.C. 336, 342(a), 346, 346a, 348, 371).

Subpart A – General Provisions

§ 509.3 Definitions and interpretations.

(a) "Act" means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms contained in section 201 of the act are applicable to such terms when used in this part unless modified in this section.

(c) A "naturally occurring poisonous or deleterious substance" is a poisonous or deleterious substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other contamination.

(d) An "added poisonous or deleterious substance" is a poisonous or deleterious substance that is not a naturally occurring poisonous or deleterious substance. When a naturally occurring poisonous or deleterious substance is increased to abnormal levels through mishandling or other intervening acts, it is an added poisonous or deleterious substance to the extent of such increase.

(e) "Food" includes pet food, animal feed, and substances migrating to food from food-contact articles.

§ 509.4 Establishment of regulations.

When appropriate under the criteria of § 509.6, a tolerance for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in Subpart B of this part under the provisions of section 406 of the act. A tolerance may prohibit any detectable amount of the substance in food.

(b)(1) When appropriate under the criteria of § 509.6, an action level for an added poisonous or deleterious substance, which may be a food additive, may be established to define the level of contamination at which a food will be deemed to be adulterated. An action level may prohibit any detectable amount of the substance in food.

(2) Whenever an action level is established, a notice shall be published in the FEDERAL REGISTER as soon as practicable thereafter. The notice shall call attention to the material supporting the action level which shall be on file with the Hearing Clerk before the notice is published. The notice shall invite public comment on the action level. Regulatory action may be taken at any time after an action level is established, and need not await publication of the notice. An action level may be changed at any time if the protection of the public health so requires. A notice shall be published in the FEDERAL REGISTER as soon as practicable after an action level is changed.

(c) A regulation may be established in Subpart C of this part to identify a food containing a naturally occurring poisonous or deleterious substance which will be deemed to be adulterated under section 402(a)(1) of the act. These regulations do not constitute a complete list of such foods.

§ 509.5 Petitions.

The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may issue a proposal to establish, revoke, or amend a regulation under this part. Any such petition shall include an adequate factual basis to support the petition, shall be in the form set forth in § 10.65 of this chapter, and will be published in the FEDERAL REGISTER for comment if it contains reasonable grounds for the proposed regulation.

§ 509.6 Added poisonous or deleterious substances.

(a) Use of an added poisonous or deleterious substance, other than a pesticide chemical, that is also a food additive will be controlled by a regulation issued under section 409 of the act when possible. When such a use cannot be approved under the criteria of section 409, or when the added poisonous or deleterious substance is not a food additive, a tolerance or action level may be established pursuant to the criteria established in paragraphs (b) and (c) of this section. Residues resulting from the use of an added poisonous or deleterious substance that is also a pesticide chemical will ordinarily be controlled by a tolerance established in a regulation issued under section 406, 408, or 409 by the U.S. Environmental Protection Agency (EPA). When such a regulation has not been issued, an action level for an added poisonous or deleterious substance that is also a pesticide chemical may

be established by the Food and Drug Administration. The Food and Drug Administration will request EPA to recommend such an action level pursuant to the criteria established in paragraph (c) of this section.

(b) A tolerance for an added poisonous or deleterious substance in any food may be established when the following criteria are met:

(1) The substance cannot be avoided by good manufacturing practice.

(2) The tolerance established is sufficient for the protection of the public health, taking into account the extent of which the presence of the substance cannot be avoided and the other ways in which the consumer may be affected by the same or related poisonous or deleterious substances.

(3) No technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance established. Examples of changes that might affect the appropriateness of the tolerance include anticipated improvements in good manufacturing practice that would change the extent to which use of the substance is unavoidable and anticipated studies expected to provide significant new toxicological or use data.

(c) An action level for an added poisonous or deleterious substance in any food may be established when the criteria in paragraph (b) of this section are met, except that technological or other changes that might affect the appropriateness of the tolerance are foreseeable in the near future. An action level shall cease to be enforced and shall be revoked when a tolerance for the same substance and use has become effective.

(d) Tolerances will be established under authority appropriate for action levels (sections 306, 402(a), and 701(a) of the act, together with section 408 or 409 if appropriate) as well as under authority appropriate for tolerances (sections 406 and 701 of the act). In the event the effectiveness of a tolerance is stayed pursuant to section 701(e)(2) of the act by the filing of an objection, the order establishing the

tolerance shall be deemed to be an order establishing an action level until the final action is taken upon such objection.

§ 509.7 Unavoidability.

(a) Tolerances and action levels in this part are established at levels based on the unavoidability of the poisonous or deleterious substances concerned and do not establish a permissible level of contamination where it is avoidable.

(b) Compliance with tolerances and action levels does not excuse failure to observe either the requirement in section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act that food may not be prepared, packed, or held under insanitary conditions or the other requirements in this chapter that food manufacturers must observe current good manufacturing practices. Evidence obtained through factory inspection or otherwise indicating such a violation renders the food unlawful, even though the amounts of poisonous or deleterious substances are lower than the currently established tolerances or action levels. The manufacturer of food must at all times utilize quality control procedures which will reduce contamination to the lowest level currently feasible.

§ 509.8 Exemptions.

(a) The Commissioner may exempt from regulatory action and permit the marketing of any food that is unlawfully contaminated with a poisonous or deleterious substance if:

(1) He determines (i) based upon all available scientific evidence, that the food is safe for consumption, and (ii) that destruction or diversion of the food involved would result in a substantial adverse impact on the national food supply.

(2) Such determination is published as a notice in the FEDERAL REGISTER and public comment shall be invited on the determination. The notice shall call attention to the material supporting the determination, which shall be on file with the Hearing Clerk before the notice is published.

(3) The determination identifies the level of contamination allowed by the exemption, and the food to which it applies, e.g., the specific growing area or other identifying information. The exemption shall not apply to any other food produced in any other area or at any other time. Contaminated food not subject to the exemption will remain subject to regulatory action.

(b) Any person responsible for contamination of the food involved, or shipment of any such food in interstate commerce prior to the issuance of an exemption pursuant to this section, shall remain subject to regulatory action pursuant to sections 302 (injunction proceedings) and 303 (penalties) of the act.

(c) In the case of a poisonous or deleterious substance which is a pesticide chemical, the level of contamination allowed by the exemption shall, upon request of the Food and Drug Administration, be specified by the Environmental Protection Agency pursuant to paragraph (a)(1)(i) of this section and promulgated by the Commissioner. No exemption for a pesticide chemical shall be promulgated without the concurrence of the Environmental Protection Agency.

§ 509.15 Use of polychlorinated biphenyls (PCB's) in establishments manufacturing food-packaging materials.

(a) Polychlorinated biphenyls (PCB's) represent a class of toxic industrial chemicals manufactured and sold under a variety of trade names, including: Aroclor (United State); Phenoclor (France); Colphen (Germany); and Kanaclor (Japan). PCB's are highly stable, heat resistant, and nonflammable chemicals. Industrial uses of PCB's include, or did include in the past, their use as electrical transformer and capacitor fluids, heat transfer fluids, hydraulic fluids, and plasticizers, and in formulations of lubricants, coatings, and inks. Their unique physical and chemical properties and widespread, uncontrolled industrial applications have caused PCB's to be a persistent and ubiquitous contaminant in the environment, causing the contamination of certain foods. In addition, incidents have occurred in which PCB's have directly contaminated animal feeds as a result of industrial accidents (leakage or spillage of PCB fluids from plant equipment). These accidents in turn caused the contamination of food products intended for human consumption (meat, milk and eggs). Investigations by the Food and Drug Administration have revealed that a significant percentage of paper food-packaging material contains PCB's which can migrate to the packaged food. The origin of PCB's in such material is not fully understood. Reclaimed fibers containing carbonless copy paper (contains 3 to 5 percent PCB's) have been identified as a primary source of PCB's in paper products. Some virgin paper products have also been found to contain PCB's, the source of which is generally attributed to direct contamination from industrial accidents from the use of PCB-containing equipment and machinery in food-packaging manufacturing establishments. Since PCB's are toxic chemicals, the PCB contamination of food-packaging materials as a result of industrial accidents, which can cause the PCB contamination of food, represents a hazard to pubic health. It is therefore necessary to place certain restrictions on the industrial uses of PCB's in establishments manufacturing food-packaging materials.

(b) The following special provisions are necessary to preclude the accidental PCB contamination of food-packaging materials:

(1) New equipment or machinery for manufacturing food-packaging materials shall not contain or use PCB's.

(2) On or before September 4, 1973, the management of establishments manufacturing food-packaging materials shall:

(i) Have the heat exchange fluid used in existing equipment for manufacturing food-packaging materials sampled and tested to determined whether it contains PCB's or verify the absence of PCB's in such formulations by other appropriate means. On or before Sept. 4, 1973, any such fluid formulated with PCB's must to the fullest extent possible commensurate with current good manufacturing practices be replaced with a heat exchange fluid that does not contain PCB's.

(ii) Eliminate to the fullest extent possible commensurate with current good manufacturing practices from the establishment any other PCB-containing equipment, machinery and materials wherever there is a reasonable expectation that such articles could cause food-packaging materials to become contaminated with PCB's either as a result of normal use or as a result of accident, breakage, or other mishap.

(iii) The toxicity and other characteristics of fluids selected as PCB replacements must be adequately determined so that the least potentially hazardous replacement is used. In making this determination with respect to a given fluid, consideration should be give to (*a*) its toxicity; (*b*) the maximum quantity that could be spilled onto a given quantity of food before it would be noticed, taking into account its color and odor; (*c*) possible signaling devices in the equipment to indicate a loss of fluid, etc.; and (*d*) its environmental stability and tendency to survive and be concentrated through the food chain. The judgment as to whether a replacement fluid is sufficiently nonhazardous is to be made on an individual installation and operation basis.

(c) The provisions of this section do not apply to electrical transformers and condensers containing PCB's in sealed containers.

Subpart B—Tolerances for Unavoidable Poisonous or Deleterious Substances

§ 509.30 Temporary tolerances for polychlorinated biphenyls (PCB's).

(a) Polychlorinated biphenyls (PCB's) are toxic, industrial chemicals. Because of their widespread, uncontrolled industrial applications, PCB's have become a persistent and ubiquitous contaminant in the environment. As a result, certain foods and animal feeds, principally those of animal and marine origin, contain PCB's as unavoidable, environmental contaminants. PCB's are transmitted to the food portion (meat, milk, and eggs) of food producing animals ingesting PCB contaminated animal feed. In addition, a significant percentage of paper food-packaging materials contain PCB's which may migrate to the packaged food. The source of PCB's in paper food-packaging materials is primarily of certain types of carbonless copy paper (containing 3 to 5 percent PCB's) in waste paper stocks used for manufacturing recycled paper. Therefore, temporary tolerances for residues of PCB's as unavoidable environmental or industrial contaminants are established for a sufficient period of time following the effective date of this paragraph to permit the elimination of such contaminants at the earliest practicable time. For the purposes of this paragraph, the term "polychlorinated biphenyls (PCB's)" is applicable to mixtures of chlorinated biphenyl compounds, irrespective of which mixture of PCB's is present as the residue. The temporary tolerances for residues of PCB's are as follows:

(1) 0.2 part per million in finished animal feed for food-producing animals (except the following finished animal feeds: feed concentrates, feed supplements, and feed premixes):

(2) 2 parts per million in animal feed components of animal origin, including fishmeal and other by-products of marine origin and in finished animal feed concentrates, supplements, and premixes intended for food-producing animals.

(3) 10 parts per million in paper food-packaging material intended for or used with finished animal feed and any components intended for animal feeds. The tolerance shall not apply to paper food-packaging material separated from the food therein by a functional barrier which is impermeable to migration of PCB's.

(b) A compilation entitled "Analytical Methodology for Polychlorinated Biphenyls, February 1973" for determining compliance with the tolerances established in this section is available from the Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, MD 20857.

NOTE: At 38 FR 22794, August 24, 1973, the following appeared concerning § 509.30(a)(9) (formerly § 122.10(a)(9)):

* * * § 509.30(a)(9) is hereby stayed pending full review of the objections and requests for hearing. * * *

In the interim, as stated in the final order (38 FR 18098) the Food and Drug Administration will enforce the temporary tolerance level established by § 509.30(a)(9) by seizing any paper food-packaging material shipped in interstate commerce after September 4, 1973 containing higher than the specified level of PCB's as adulterated in violation of sec. 402 of the act.

Subpart C—Naturally Occurring Poisonous or Deleterious Substances—[Reserved]

Effective date: These regulations shall become effective October 31, 1977.

Dated: September 23, 1977.

DONALD KENNEDY,
Commissioner of Food and Drugs.

[FR Doc. 77-28576 Filed 9-29-77; 8:45 am]

[4110-03]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[Docket No. 78N-0062]

AFLATOXIN-CONTAMINATED CORN

Limited Exemption From Blending Prohibition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This document grants certain States a limited exemption from a blending prohibition. This exemption applies to aflatoxin-contaminated corn. The blended corn must not exceed an action level and may be used only in certain animal feed. This action is taken to avert a substantial adverse impact on the national food supply.

EFFECTIVE DATES: April 4, 1978; expiration date: This exemption shall remain in effect until January 1, 1979.

FOR FURTHER INFORMATION CONTACT:

Caesar A. Roy, Bureau of Foods (HFF-310), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-245-1186.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration is establishing a limited exemption to its prohibition against blending a food (corn) containing a poisonous or deleterious substance (aflatoxin) in amounts above the tolerance or action level (20 parts per billion (20 ppb)) with less contaminated food to obtain a mixture within the tolerance or action level. This exemption applies to corn harvested in 1977 in the States of Alabama, Florida, Georgia, Mississippi, North Carolina, South Carolina, and Virginia. The blending must be done in accordance with a technically feasible plan approved by the FDA Regional Office in Atlanta, Ga., before blending operations begin. The exemption does not apply to corn that contains more than 20 ppb aflatoxin if the corn has been shipped in interstate commerce. The blended corn must not exceed the action level of 20 parts per billion (ppb) aflatoxin and must be used only for animal feed for mature poultry and swine, and mature, non-milk-producing beef cattle. This exemption does not apply to corn or mixed feeds used for rations for dairy animals, or starter rations for very young animals, or to corn for human consumption.

Corn that contains aflatoxin in excess of the established FDA action level of 20 parts per billion (ppb) is an adulterated food under section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1)). Use of an adulterated food as an ingredient in another food ordinarily causes the finished food to be deemed adulterated, even if the finished product itself does not violate an established tolerance or action level.

The action level for aflatoxin applies only to unavoidable contamination of corn. Intentional blending of a violation article with an uncontaminated article is wholly avoidable and not authorized by the action level. Any aflatoxin contamination that can be shown to have occurred as a result of inadequate postharvest drying or faulty storage will be considered avoidable and therefore, not authorized by the tolerance.

Section 509.8 (21 CFR 509.8), issued in the FEDERAL REGISTER of September 30, 1977 (42 FR 52822), provides for exemptions from established action levels if the Commissioner of Food and Drugs determines that (1) based on all available evidence, the food is safe for consumption, and (2) destruction or diversion of the food involved would result in a substantial adverse impact on the national food supply.

The Commissioner has reviewed all available evidence concerning the safety of aflatoxin in feed corn and has determined that the limited exemption to permit blending established by this notice will not result in any perceivable increased risk to the health of mature poultry and swine and mature non-milk-producing beef cattle fed such corn, or to humans consuming edible tissues derived from those animals.

The Commissioner has determined that the destruction or diversion of corn that would be required by the continued prohibition of blending of the subject feed corn would result in a substantial impact on the national food supply.

Based on data recently compiled by FDA, over half the 1977 corn crop in parts of the Southeast United States (Alabama, Georgia, Florida, Mississippi, North Carolina, South Carolina, and Virginia) may exceed the 20 ppb ac-

tion level and thus may not be shipped in interstate commerce. Since it may be difficult for farmers in this area to find adequate suppliers of corn for use in feeding animals if the law is enforced fully, the Commissioner has determined that he will not recommend regulatory action for violation of the Federal Food, Drug, and Cosmetic Act with respect to blending of such corn for use as animal feed if conditions of this notice are met.

It is anticipated that permitting the blending of feed corn under the terms of the exemption from the 20 ppb action level stated in this notice will increase the marketable feed corn crop in the seven States where blending will be allowed. This increase may be as much as 111.4 million bushels, valued at 235.5 million dollars at current support prices.

FDA has advised the States in the southeastern United States that intrastate corn containing up to 100 ppb aflatoxin may safely be used for animal feed for mature poultry and swine, and mature, non-milk-producing beef cattle if the State can ensure that the corn will not be diverted to other uses. Some States have told FDA that they cannot monitor the use of the corn closely enough to ensure that the limitation is adhered to; FDA has then advised the State not to permit corn containing more than 20 ppb aflatoxin to be used for any purpose. The exemption stated in this notice requires that the corn contain no more than 20 ppb after blending rather than 100 ppb because FDA cannot monitor the flow of corn in interstate commerce to the extent necessary to ensure that the corn is used in accordance with the terms of the exemption. Permitting corn containing up to 100 ppb aflatoxin to be shipped in interstate commerce would present an unreasonable risk that the corn would be used to feed dairy animals or very young animals, or that it would be used for food for human consumption.

The Commissioner is not altering the agency's long-standing position that it is ordinarily unlawful to blend corn containing aflatoxin above the action level with less contaminated corn. But the Commissioner is permitting blending on a one-time basis only because of the severity of this emergency situation.

Therefore, the Commissioner gives notice pursuant to § 509.8 (21 CFR 509.8) of the following exemption from the action level for aflatoxin:

Notice of Exemption

(a) The Food and Drug Administration will not recommend regulatory action against corn containing aflatoxin for violation of the Federal Food, Drug, and Cosmetic Act with respect to blending of corn containing aflatoxin in excess of 20 ppb if all the following conditions are met:

1. The contaminated corn was harvested in 1977 in the States of Alabama, Florida, Georgia, Mississippi, North Carolina, South Carolina, and Virginia.

2. Aflatoxin contamination did not result from improper agricultural, storage, shippping, or manufacturing practices.

3. A technically feasible plan for blending has been approved by the FDA Regional Office in Atlanta, Georgia, before blending operations begin. It must be demonstrated that the blending plan can reasonably be expected to result in a finished lot of corn containing not more than 20 ppb of aflatoxin. The blending must be accomplished under Federal or State supervision, and the finished lot must be approved by Federal or State authorities before shipment in interstate commerce. It must be demonstrated to the satisfaction of the supervising Federal or State authority that the aflatoxin level of the blended lot is not above 20 ppb.

4. The aflatoxin-contaminated corn must not have been shipped in interstate commerce prior to FDA approval of the blending plan. (If the FDA were to approve blending of corn after shipment in interstate commerce, there would be an unacceptable risk that some persons might ship contaminated corn in interstate commerce and blend only if the contaminated shipments were detected by Federal or State authorities).

5. The corn containing aflatoxins in excess of 20 ppb is mixed with noncontaminated corn resulting in a mixture containing no more than 20 ppb total aflatoxins.

6. The blended lot must be offered for use only for animal feed for mature poultry and swine and for non-milk-producing beef cattle. It may not be used to feed dairy animals or very young animals, and it may not be used for human consumption.

(b) In all other cases, the existing 20 ppb action level for aflatoxin contamination will be applied.

Assessments of safety and impact on the national food supply, including references and supporting data upon which this notice is based, are on file with the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

Public comment is invited on any or all aspects of this notice and the Commissioner's determinations herein. Comments may be sent to the Hearing Clerk (address above) and will be received while this notice remains in effect.

This notice will be in effect until January 1, 1979.

Dated: March 24, 1978.

JOSEPH P. HILE
Acting Commissioner,
Food and Drug Administration.

[FR Doc. 78-8586 Filed 3-29-78; 10:06 am]

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 80-3110

COMMUNITY NUTRITION INSTITUTE,
1146 19TH STREET, N.W.,
WASHINGTON, D.C. 20036, (202) 833-1730

PUBLIC CITIZEN, 1346 CONNECTICUT AVENUE, N.W.,
WASHINGTON, D.C. 20036, (202) 293-9142

LINDA S. BARDOT, 8531 FOREST STREET, ANNANDALE,
VIRGINIA 22003 (703) 978-2306

AND

LAURA A. ROGERS, 2730 WISCONSIN AVENUE, N.W.,
WASHINGTON, D.C. 20007, (202) 338-5608
PLAINTIFFS,

v.

JERE GOYAN, COMMISSIONER, FOOD AND DRUG
ADMINISTRATION, 5600 FISHERS LANE, ROCKVILLE,
MARYLAND 20852, DEFENDANT

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. This action seeks a declaratory judgment and order enjoining a pattern of continuing violations of law in defendant's regulation of the interstate sale of corn adulterated with aflatoxin, a potent carcinogen.

JURISDICTION

2. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331.

PARTIES

3. Defendant Jere Goyan is Commissioner of the Food and Drug Administration ("FDA") and is responsible for administering the Federal Food, Drug and Cosmetic Act, which prohibits the sale of adulterated food in interstate commerce. 21 U.S.C. § 331(a).

4. Plaintiff Community Nutrition Institute ("CNI") is a non-profit public interest organization which promotes the formation of a sound food policy that serves the health needs of consumers at the community level. CNI has long been active in opposing the sale of foods containing unsafe additives and other ingredients, and in a letter to the defendant dated October 6, 1980, specifically opposed the FDA policies now challenged in this case. CNI is supported, in part, by annual contributions in the form of subscriptions from approximately 6,000 persons. CNI brings this action on behalf of its supporters and also its approximately 28 employees, most or all of whom consume corn and related corn products, and milk and meat from animals which consume corn as feed.

5. Plaintiff Public Citizen is a non-profit, public interest organization supported by annual contributions from approximately 40,000 persons. Its Health Research Group ("HRG") is engaged in research and advocacy to promote safe food and drugs, and it has long opposed the sale of aflatoxin-contaminated food products. In 1975 it submitted comments in response to FDA's proposal to lower the tolerance level for aflatoxin in peanuts. Public Citizen brings this action on behalf of its contributors and on behalf of its approximately 52 employees, most or all of whom consume corn and related corn products, and milk and meat from animals which consume corn as feed.

6. Plaintiff Linda S. Bardot is an employee of CNI. She and her family, which includes two children ages 8 and

5, regularly eat corn and foods containing corn meal, and also drink milk and eat poultry, beef and pork, which come from animals fed on corn.

7. Plaintfiff Laura A. Rogers regularly eats corn and foods containing corn meal, and also drinks milk and eats poultry, beef and pork, which come from animals fed on corn.

STATUTORY AND REGULATORY FRAMEWORK

8. Section 301(a) of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), 21 U.S.C. § 331(a), prohibits the interstate shipment of "adulterated food. Adulterated food is defined as, among other things, food containing "any poisonous or deleterious substance which may render it injurious to health." 21 U.S.C. § 342(a)(1).

9. Section 406 of the FDC Act, 21 U.S.C. § 346, provides that when a poisonous or deleterious substance cannot be avoided, the Secretary shall set a formal tolerance level for such substance by promulgating regulations limiting the quantity "to such extent as he finds necessary for the protection of public health."

10. FDA's regulations prohibit the mixing or "blending" of a food contaminated above the current tolerance level with another lot of food not so contaminated, and state that such blending renders the final food adulterated regardless of the contamination level of the final food. 21 C.F.R. § 110.99(d).

FACTS GIVING RISE TO PLAINTIFFS' CLAIMS FOR RELIEF

11. Aflatoxin is a poison produced by a natural mold which grows on corn and other agricultural products, particularly in certain states in the southeastern portion of the United States. Aflatoxin is among the most potent carcinogens known in laboratory animals. There are also

positive correlations between dietary aflatoxins and primary human liver cancer. There is no known level of aflatoxin exposure which is considered safe for humans.

12. Since the early 1960's, FDA has considered corn and other products contaminated with certain levels of aflatoxin to be adulterated within the meaning of the FDC Act. However, FDA's program for the control of aflatoxin exposure demonstrates systematic and continuing violations of the FDC Act, the Administrative Procedure Act, and FDA's regulations.

13. FDA has never established a formal tolerance level for aflatoxin contamination in agricultural products, as required by section 406 of the FDC Act. Instead, FDA has set an informal action level, which is an administrative determination, without notice and comment rulemaking, as to the level of aflatoxin contamination below which no regulatory action will be taken against a product. Since 1969, the action level for aflatoxin in agricultural products, whether sold for human consumption or for animal feed, has been 20 parts per billion (ppb).

14. In 1978, contrary to its own regulations, FDA permitted the blending of corn contaminated with levels of aflatoxin in excess of 20 ppb with corn not so contaminated, provided the final product contained less than 20 ppb of alfatoxin. While affirming its long-standing position that it is unlawful to blend adulterated corn with less contaminated corn to achieve a product within the action level, FDA nevertheless permitted, on what it characterized as a "one-time basis only," the interstate shipment of blended corn from various states for use as feed for certain animals. 43 F.R. 14122-14123 (April 4, 1978).

15. In the fall of 1980, FDA again permitted the blending of aflatoxin-contaminated corn, this time approving the shipment and the sale of blended corn containing up to 100 ppb aflatoxin, 5 times the previously

allowable limit, for use as feed for certain animals. FDA granted this approval by way of telegrams to the Agricultural Departments of the states of North Carolina, South Carolina and Virginia. FDA provided no notice or opportunity for comment on this action.

PLAINTIFFS' CAUSES OF ACTION

16. FDA's approval of aflatoxin in corn by use of an informal action level is contrary to section 406 of the FDC Act, 21 U.S.C. § 346, which provides that tolerances shall be established by rulemaking.

17. FDA's approval of the intentional blending of adulterated corn, containing aflatoxin in excess of its long-standing action level, with corn not so contaminated is contrary to its own regulations, 21 C.F.R. § 110.99(d), and to the FDC Act, which permits the establishment of tolerance levels for poisonous or deleterious substances, but only if those substances are unavoidably present in food. 21 U.S.C. § 346.

18. FDA's approval of a five-fold increase in the action level of aflatoxin-contaminated corn used as feed for certain animals constitutes the approval of the shipment in interstate commerce of adulterated food, contrary to the FDC Act, 21 U.S.C. §§ 331 and 342.

19. FDA's approval of the shipment of corn containing up to 100 ppb aflatoxin is arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with law within the meaning of section 10(e) of the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2), in view of the unreasonable risk that humans will consume significantly increased amounts of aflatoxin either in the meat or milk from animals fed such corn, or in products manufactured from such corn.

20. FDA's approval of a five-fold increase in its long-standing action level for aflatoxin of 20 ppb without notice and opportunity for comment is contrary to the Administrative Procedure Act, 5 U.S.C. § 553.

21. Linda S. Bardot, Laura A. Rogers, and the members, supporters, and employees of CNI and Public Citizens are aggrieved by FDA's actions in that, as a result, they and their families will consume increased amounts of aflatoxin. CNI, Public Citizen and the individual plaintiffs have also been deprived of the opportunity to comment on FDA's actions and of the additional protections that the FDC Act provides with respect to the establishment of formal tolerance levels for poisonous and deleterious substances in food.

22. Unless enjoined by this Court, FDA will continue a pattern and practice of violations of law in the regulation of aflatoxin-contaminated corn and plaintiffs will continue to suffer the kind of harms described in paragraph 21.

WHEREFORE, plaintiffs seek an order from this Court:

a) declaring that FDA has acted in violation of the FDC Act, the Administative Procedure Act and its own regulations by:

i) approving certain levels of aflatoxin in corn by use of an informal action level, rather than setting a formal tolerance through rulemaking,

ii) approving the blending of aflatoxin-contaminated corn, and

iii) approving a five-fold increase in the action level for aflatoxin-contaminated corn for certain uses, without notice and opportunity for comment;

b) enjoining FDA from approving or permitting the shipment in interstate commerce of corn contaminated with more than 20 ppb aflatoxin pending completion of a formal rulemaking, or of corn which has been blended with such contaminated corn;

c) granting plaintiffs their costs and disbursements in this action; and

d) providing for such other relief as may be just and proper.

Respectfully submitted,

/s/
Diane B. Cohn

/s/
William B. Schultz

/s/
Alan B. Morrison

Suite 700
200 P Street, N.W.
Washington, D.C. 20036
(202) 785-3704

Attorneys for Plaintiffs

December 5, 1980

[Docket No. 80N-0520]

AFLATOXIN-CONTAMINATED CORN: LIMITED EXEMPTIONS FROM PROHIBITION OF INTERSTATE SHIPMENT AND BLENDING

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This document announces that !imited exemptions have been granted to the State of North Carolina and South Carolina and the Commonwealth of Virginia from the Food and Drug Administration's (FDA's) prohibition of interstate shipment and blending of corn containing aflatoxin in excess of the agency's action level of 20 parts per billion (ppb). Corn containing up to 100 ppb aflatoxin may be shipped in interstate commerce under plans which were developed by the three States and approved by FDA. The plans assure that such corn does not contain more than 100 ppb aflatoxin and is not diverted for uses other than as feed for mature, nonlactating livestock and mature poultry. Blending of corn to achieve levels of no more than 100 ppb aflatoxin is permitted under certain controlled conditions. These exemptions were granted to avert a substantial adverse impact on the national food supply.

EFFECTIVE DATES: October 9, 1980—North and South Carolina; November 5, 1980—Virginia.

EXPIRATION DATE: The exemptions apply only to the 1980 corn crop in North Carolina, South Carolina, and Virginia, and shall remain in effect until January 1, 1982.

FOR FURTHER INFORMATION CONTACT: Taylor M. Quinn, Bureau of Foods (HFF-300), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-1243.

SUPPLEMENTARY INFORMATION: In response to requests from the States of North Carolina and South Carolina and the Commonwealth of Virginia, FDA is establishing limited exemptions to its prohibition of interstate shipment and blending of corn containing aflatoxin above its action level of 20 ppb. These exemptions apply only to the 1980 corn crop harvested in the States of North Carolina and South Carolina and the Commonwealth of Virginia and allow the interstate shipment of corn containing up to 100 ppb aflatoxin to be used only for feed for mature, nonlactating livestock and mature poultry. These exemptions do not apply to corn or mixed feeds used for rations for lactating dairy animals, or starter rations for very young animals, or to corn for human consumption. Corn containing more than 20 ppb may be blended with less contaminated corn to achieve a total aflatoxin level of no more than 100 ppb.

Any food that contains aflatoxin in excess of 20 ppb (FDA Administrative Guidelines Manual, 7420.01 (5/15/79)) is considered by FDA to be adulterated under section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act. (21 U.S.C. 342(a)(1)), and therefore may not be shipped in interstate commerce. Also, use of an adulterated food as an ingredient in another food causes the finished food to be deemed adulterated, even if the finished food itself does not violate an established action level.

The 20 ppb action level for aflatoxin applies only to unavoidable contamination of food. Thus, the intentional blending of a violative food with an uncontaminated food is not authorized by the action level.

FDA's regulations on unavoidable contaminants in animal food and food-packaging material, 21 CFR 509.8, provide for exemptions from regulatory action if the Commissioner of Food and Drugs determines that (1) based on all available evidence, the food is safe for consumption,

that is, a significant health hazard is not involved, and (2) destruction or diversion of the food involved would result in a substantial adverse impact on the national food supply.

The agency has reviewed all available evidence concerning the effects on the health of animals consuming aflatoxin contaminated corn and humans consuming food derived from these animals. The agency has determined that the limited exemptions specified in this notice will not result in any adverse effects to the health of mature, nonlactating liverstock and mature poultry fed such corn, and will not pose a significant health hazard or even a significant increase in risk to humans consuming edible products derived from these animals.

The agency has determined that the destruction or diversin of corn that would be required by the continued prohibition of interstate shipment and blending of the subject feed corn would result in a substantial adverse impact on the national food suply.

In the **Federal Register** of April 4, 1978 (43 FR 14122) FDA established a limited exemption to its prohibition against blending corn containing aflatoxin above its action level of 20 ppb with less contaminated corn to achieve a mixture below 20 ppb. The exemption applied only to corn harvested in 1977 in the southeast United States and was granted to avert a substantial adverse impact on the national food supply. In the 1978 notice, FDA stated that it had advised the States in the southeastern United States that "intrastate corn containing up to 100 ppb aflatoxin may be used safely for animal feed for mature poultry and swine, and mature, non-milk-producing beef cattle" if the State could ensure that the corn would not be diverted to other uses. FDA explained that the exemption required that the corn contain no more than 20 ppb after blending rather than 100 ppb "because FDA cannot monitor the flow of corn in interstate commerce to the extent necessary

to ensure that the corn is used in accordance with the terms of the exemption. Permitting corn containing up to 100 ppb aflatoxin to be shipped in interstate commerce would present an unreasonable risk that the corn would be used to feed dairy animals or very young animals, or that it would be used for food for human consumption."

Analyses of samples of the 1980 corn crop from the States of North Carolina and South Carolina and the Commonwealth of Virginia reveal that aflatoxin contamination in those States is at least as great as, if not greater than, the aflatoxin contamination in the 1977 corn crop harvested in parts of the southeast United States. North Carolina, South Carolina, and Virginia, estimate that 63, 73, and up to 23 percent of their 1980 corn crop, respectively, may contain more than 20 ppb aflatoxin and therefore may not be shipped in interstate commerce for food or feed use.

As part of their requests for exemptions from the current action level of 20 ppb aflatoxin, North Carolina, South Carolina, and Virginia have submitted to FDA detailed control plans to ensure that corn containing up to 100 ppb alfatoxin when shipped in interstate commerce is not diverted for uses other than as feed for mature, nonlactating livestock and mature poultry. Accordingly, FDA has agreed to permit (1) the shipment in interstate commerce of corn from the 1980 crop and which contains up to 100 ppb aflatoxin when such corn is shipped in accordance with those plans and (2) the blending of corn to achieve levels of aflatoxin of up to 100 ppb when such blending is done under certain controlled conditions. FDA anticipates that permitting the interstate shipment and blending of corn under the terms of the exemptions stated in this notice will increase the marketable feed corn crop in North Carolina, South Carolina, and Virginia. This increase is estimated at 101.4 million bushels, valued at 319.5 million dollars at current market prices.

The agency has determined that it will not recommend regulatory action for violation of the Federal Food, Drug, and Cosmetic Act with respect to the interstate shipment of corn from the 1980 crop harvested in North Carolina, South Carolina, and Virginia and which contains no more than 100 ppb aflatoxin; or with respect to the blending of corn to achieve a level of no more than 100 ppb aflatoxin, provided the conditions set out in this notice are met. FDA emphasizes, however, that it is not altering the agency's longstanding positions that it is unlawful to ship in interstate commerce corn containing more than 20 ppb aflatoxin and that it is unlawful to blend corn containing more than 20 ppb aflatoxin with less contaminated corn and ship the blended corn in interstate commerce. The agency is permitting the exemptions set out in this notice on a one-time basis for the 1980 corn crop harvested in North Carolina, South Carolina, and Virginia only because of the severity of this emergency situation.

Therefore, the Commissioner gives notice pursuant to § 509.8 [21 CFR 509.8] of the following exemptions:

Notice of Exemptions

a. The Food and Drug Administration will not recommend regulatory action against corn from the 1980 corn crop harvested in North Carolina, South Carolina, and Virginia and which contains between 20 ppb and 100 ppb aflatoxin or corn blended to achieve a level of no more than 100 ppb aflatoxin for violation of the Federal Food, Drug, and Cosmetic Act, provided the following terms and conditions of plans submitted to FDA by the three States have been met:

1. All corn handled in the manner described in the States' plans shall be used only for feeding of mature, nonlactating livestock and mature poultry.

2. Upon notification by a firm of its intention to ship in interstate commerce corn containing between 20 ppb and 100 ppb aflatoxin, the State of origin's Department of Agriculture shall obtain from the intended shipper a history of the corn and shall collect samples of all lots of the corn.

3. The lot (i.e., individually-characterized mass of corn, compartmentalized and ready for shipment to purchaser) or corn shall either be stream-sampled at intervals during the entire loading process to obtain at least a ten-pound sample or randomly-sampled with appropriate-size commercial grain probes to obtain at least a ten-pound sample that is representative of the lot.

4. The entire sample shall be the ground, mixed, and analyzed by the State laboratories as prescribed in the "Official Methods of Analyzed of the Association of Official Analytical Chemists," 13th ed. 1980.

5. The test acceptance level for each lot shall be 80 ppb or less. For stream-sampled corn, a single analysis is sufficient; for randomly sampled corn, a duplicate analysis shall be performed, the average result of which may not exceed the 80 ppb level. Under this system, there is a 95 percent or greater probability that a lot of corn which contains a true mean of 100 ppb or more aflatoxin will be rejected.

6. Each lot of corn shall be labeled at all times with the name and address of the purchaser and of the seller, the aflatoxin content, and the phrase "To be fed only to nonlactating mature livestock and/or mature poultry". Any invoice and bill of lading shall also be marked with this information. In addition, the bill of lading shall bear the seal numbers or other identification to relate the bill of lading to the lot.

7. The Department of the Agriculture of the State of origin shall maintain records for a period of at least one year after obtaining the samples. Such records shall in-

clude, but not be limited to information showing: the origin of the corn, the date sampled, the aflatoxin content, the destination, how the corn shipped from the State of origin to the receiving State was controlled to prevent diversion (e.g., railcar seals), and the intended use of the corn at its destination.

8. The State of origin shall have a prearranged agreement with the appropriate regulatory agency in the State to which corn is to be shipped. This agreement shall specify the means by which the designated regulatory agency in the receiving State intends to assure proper disposition of the corn. As a part of the agreement, the receiving State shall written notification from each buyer (ultimate user) that the corn shall be fed only to mature nonlacting livestock or mature poultry. The State of origin shall also notify FDA of each lot of corn to be shipped and the destination of each lot. The receiving State shall agree to notify the State of origin and FDA when such shipments are received. The receiving State shall maintain records documenting the final and proper disposition of the corn by the ultimate user.

9. Before a lot of "blended" corn (i.e., corn which because of its high aflatoxin content has been mixed with other corn to reduce its aflatoxin content below 100 ppb) is shipped in interstate commerce, the responsible firm shall submit to the Department of Agriculture of the State of origin a plan that describes how uniform blending is to be accomplished, the aflatoxin content of the contaminated corn and the blended corn, methods to be used for sampling and analysis, and the moisture content of both lots of corn. The State Department of Agriculture shall review and, if appropriate, approve the plan, and notify the firm of any changes which must be made. The State Department of Agriculture shall forward a copy of the approved plan to the appropriate FDA Regional Office, and maintain records for inspection by FDA. The final lots shall be

sampled and analyzed by the Department of Agriculture of the State of origin as outlined in Steps 3 and 4 above and 11 below.

10. Corn in excess of 400 ppb aflatoxin shall not be used for blending.

11. Two ten-pound samples shall be randomly and representatively drawn from any lot of aflatoxin-contaminated corn which has been blended with other corn to achieve a level below 100 ppb aflatoxin. Both samples shall be analyzed in duplicate. The average of the duplicate analysis of the two ten-pound samples may not differ more than 50 ppb aflatoxin. The average four analysis may not exceed 80 ppb aflatoxin. If either of the assay criteria for blended corn is not met, the blending shall be classified as unacceptable. Reblending will be permitted.

12. Certification of the aflatoxin content of any lot of corn by the State or origin shall be made before interstate shipment.

13. Copies of the approved State plans for carrying out the FDA exemptions shall be distributed to all elevators merchandising corn in the affected States.

b. In all other cases the FDA's prohibition of interstate shipment and blending of corn containing aflatoxin in excess of the agency's 20 ppb action level will be applied.

All correspondence between the States of North Carolina and South Carolina and the Commonwealth of Virginia and FDA, including the State plans; and assessment of safety and impact on the national food supply, including references and supporting data upon which this notice is based, are on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

Public comment is invited on this notice and the Commissioner's determinations herein. Comments may be sent

to the Dockets Management Branch (address above) and will be received while this notice remains in effect.

This notice shall remain in effect until January 1, 1982.

Dated: January 19, 1981.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 81-2604 Filed 1-22-81; 8:45 am]

BILLING CODE 4110-03-M

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 80-3110

COMMUNITY NUTRITION INSTITUTE, ET AL., PLAINTIFFS,

v.

JERE GOYAN, COMMISSIONER, FOOD AND DRUG ADMINISTRATION, DEFENDANT.

ANSWER

First Defense

The Complaint fails to state a claim upon which relief may be granted.

Second Defense

This Court lacks jurisdiction over the subject matter of this action because the acts complained of are committed to agency discretion by law.

Third Defense

This Court lacks jurisdiction over the subject matter of this action because plaintiffs have failed to exhaust their administrative remedies.

Fourth Defense

This Court lacks jurisdiction over the subject matter of this action because none of the plaintiffs participated in a notice-and-comment rulemaking proceeding of the Food and Drug Administration ("FDA") which resulted in regulations that cover the acts about which plaintiffs complain.

Fifth Defense

Answering specifically the numbered paragraphs of the Complaint, using the same numbering, defendant states as follows:

1. Paragraph 1 contains plaintiffs' characterization of the action to which no response is required. To the extent an answer is deemed necessary, paragraph 1 is denied.

2. Paragraph 2 is denied because it consists of a conclusion of law.

3. Defendant admits that the Commissioner of Food and Drugs is responsible for administering the Federal Food, Drug and Cosmetic Act, but respectfully refers the Court to 21 U.S.C. § 331(a) for a complete and accurate statement of its contents. Defendant also admits that at the time this action was filed Jere Goyan was Commissioner of FDA.

4. Paragraph 4 is denied except to admit the receipt of the letter from plaintiff Community Nutrition Institute dated October 6, 1980. The denial of the other allegations in paragraph 4 is based on defendant's lack of knowledge sufficient to form a belief as to their truth.

5. Paragraph 5 is denied except to admit that in 1975 the Health Research Group submitted comments on FDA's "Proposed Tolerance; Aflatoxins in Shelled Peanuts and Peanut Products used as Human Food," 39 Fed. Reg. 42478 (December 6, 1974). The denial of the other allegations of paragraph 5 is based on defendant's lack of knowledge sufficient to form a belief as to their truth.

6-7. Defendant is without knowledge sufficient to form a belief as to the truth of the allegations of paragraphs 6 and 7. Paragraphs 6 and 7 are therefore denied.

8-10. Paragraphs 8, 9, and 10 are denied because they consist of conclusions of law. The Court is respectfully

referred to 21 U.S.C. §§ 331(a), 342(a)(1), 346, and 21 C.F.R. § 110.99(d) for a complete and accurate statement of their contents.

11. Defendant admits the first and second sentences of paragraph 11. With respect to the third sentence, defendant admits only that there are epidemiological studies which report positive correlations between dietary aflatoxins and primary human liver cancer. With respect to the fourth sentence, defendant admits only that there is no known level of aflatoxin exposure which has been proved to be safe for humans.

12. Defendant denied paragraph 12 except to admit that since the early 1960's, FDA has considered food containing aflatoxin in excess of certain amounts to be adulterated within the meaning of 21 U.S.C. §342(a)(1).

13. With respect to the first sentence of paragraph 13, defendant admits that FDA has never established, by regulations, a formal tolerance for aflatoxin in food, but denies that 21 U.S.C. §346 requires FDA to establish, by regulations, a formal tolerance for aflatoxin in food. The second and third sentences of paragraph 13 are admitted.

14. Paragraph 14 is admitted except to deny that the act complained of violated any FDA regulations. Defendant further states that the action taken was taken pursuant to and in accordance with 21 C.F.R. § 509.8.

15. Paragraph 15 is admitted except to deny that FDA provided no notice or opportunity for comment on the acts complained of. Defendant further states that notice and comment was provided for in 46 Fed. Reg. 7447-7449 (January 23, 1981). That notice expressly solicits comments on the exemptions which were granted pursuant to and in accordance with 21 C.F.R. § 509.8.

16-18. Paragraph 16, 17, and 18 are denied because they consist of conclusions of law. The Court is respectfully referred to the specific statutory and regulatory provisions cited for a complete and accurate statement of their contents.

19. Paragraph 19 is denied because it consists of conclusions of law. Further, defendant specifically denies the allegation that there is an unreasonable risk to humans or that humans will consume significant increased amounts of aflatoxin as a result of FDA's action. 46 Fed. Reg. 7447-49 (January 23, 1981).

20-22. Paragraphs 20, 21, and 22 are denied because they consist of conclusions of law.

The remaining portions of the Complaint contain plaintiffs' prayer for relief to which no response is required. To the extent a response is deemed necessary, the remaining portions of plaintiffs' Complaint are denied.

Any allegations not specifically admitted are hereby denied.

The defendant respectfully requests the Court to dismiss the action and grant the defendant his costs.

Respectfully submitted,

/s/
CHARLES F. C. RUFF
United States Attorney

/s/
ROYCE C. LAMBERTH
Assistant United States Attorney

/s/
PATRICIA J. KENNEY
Assistant United States Attorney
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Attorneys
Food and Drug Administration

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 80-3110

COMMUNITY NUTRITION INSTITUTE, ET AL., PLAINTIFFS,

v.

JERE GOYAN, COMMISSIONER, FOOD AND DRUG ADMINISTRATION, DEFENDANT.

DEFENDANT'S ANSWERS TO PLAINTIFFS' INTERROGATORIES

INTERROGATORY NO. 1

Identify all Federal Register notices, Code of Federal Regulations citations or other documents which propose or establish an action level for aflatoxin in food products.

ANSWER

i) February 15, 1965, Program Circular 16A-1 "Aflatoxin in Peanuts and Peanut Products."
ii) October 3, 1969 Memorandum from J. K. Kirk, FDA to Directors of Districts, FDA, "Aflatoxin in Peanuts and Peanut Products."
iii) The Federal Register of December 6, 1977 (42 FR 61630), *Aflatoxin Contamination of Milk*.
iv) FDA Administrative Guidelines Manual, 7412.01, Aflatoxin in Brazil nuts.
v) FDA Administrative Guidelines Manual, 7420.01, Aflatoxin in Foods and Feeds.

vi) FDA Administrative Guidelines Manual, 7406.06, Aflatoxin in Milk.
vii) FDA Administrative Guidelines Manual, 7412.03, Aflatoxin in Peanuts and Peanut Products.
viii) FDA Administrative Guidelines Manual, 7412.05, Aflatoxin in Pistachio Nuts.

FDA is diligently searching for any additional documents which are required under this interrogatory.

INTERROGATORY NO. 2

a) State whether the Food and Drug Administration ("FDA") has established a formal tolerance level for aflatoxin contamination in food. b) State whether FDA has ever considered the establishment of a formal tolerance level for aflatoxin in food, and, if so, identify all documents which reflect or refer to FDA's consideration of whether or not to set a formal tolerance.

ANSWER

2. a) No
b) FDA has considered the establishment of a formal tolerance for aflatoxin in peanuts. (See the Federal Register of December 6, 1974, 39 F.R. 42748; the Federal Register of March 3, 1978, 43 F.R. 8808).

INTERROGATORY NO. 3

List all tolerance levels for poisonous or deleterious substances established pursuant to 21 U.S.C. § 346 and identify all Federal Register or other documents or Code of Federal Regulations citations which establish such tolerance levels.

ANSWER

3. Tolerances for polychlorinated biphenyls (PCB's) in animal feeds, foods, and food-packaging materials were established July 6, 1973 (38 F.R. 18096):

i) 2.5 ppm in milk (fat basis).
ii) 2.5 ppm in manufactured dairy products (fat basis).
iii) 5 ppm in poultry (fat basis).
iv) 0.5 ppm in eggs.
v) 0.2 ppm in finished animal feed for food-producing animals (except the following finished animal feeds: feed concentrates, feed supplements, and feed premixes).
vi) 2 ppm in animal feed components of animal origin, including fishmeal and other by-products of marine origin and in finished animal feed concentrates, supplements, and premixes intended for food producing animals.
vii) 5 ppm in fish and shell fish (edible portion). The edible portion of fish excludes head, scales, viscera, and inedible bones.
viii) 0.2 ppm in infant and junior foods.
ix) 10 ppm in paper food-packaging material intended for or used with human food, finished animal feed and any components intended for animal feeds. The tolerance shall not apply to paper food-packaging material separated from the food therein by a functional barrier which is impermeable to migration of PCB's.

The tolerance for PCB's in several classes of food were changed by Final Rule, June 29, 1979 (44 F.R. 38330):

i) 1.5 ppm in milk (fat basis).
ii) 1.5 ppm in manufactured dairy products (fat basis).
iii) 3 ppm in poultry (fat basis).
iv) 0.3 ppm in eggs.
v) 2 ppm in fish and shellfish (edible portion).

The tolerances for PCBs in paper food-packaging materials intended for or used with human food, finished

animal feed, and any components intended for animal feeds were stayed on August 24, 1973 (38 F.R. 22794) pending full review of the objections and request for hearing.

The tolerance for PCBs in fish and shellfish was stayed until further notice on October 5, 1979 (44 F.R. 57389).

INTERROGATORY NO. 4

List all action levels set with respect to any substances in food and identify all Federal Register notices or other documents or Code of Federal Regulations citations which establish such action levels.

ANSWER

4. Defendant objects to this interrogatory on the ground that it is not reasonably calculated to lead to the discovery of admissible evidence because the actions complained about in this case deal solely with aflatoxin in corn. Rule 26(b), Federal Rules of Civil Procedure. Information concerning FDA action levels for other substances in other foods is irrelevant and cannot lead to admissible evidence. Insofar as an answer to this interrogatory is deemed to be required, and without waiving its objection, FDA has attached a list (see exhibit 1) of all action levels for poisonous and deleterious substances in food. Defendant further objects to the identification of all Federal Register notices or other documents or Code of Federal Regulation citations which establish such action levels on the ground that such identification is not capable of leading to the discovery of admissible evidence and is unduly burdensome because the information regarding the Federal Register notices or Code of Federal Register citations and the custody of the "other documents" is widely dispersed throughout the agency and there is no one individual or group of individuals who possess this information.

INTERROGATORY NO. 5

For each application which has ever been made to the FDA for permission to ship corn which contains aflatoxin at levels in excess of 20 ppb or which has been blended, provide the following information:

a. identify the application and state who submitted it;

b. describe the terms of the approval requested, including the geographic area to which it would apply, the duration of the shipments, and the level of aflatoxin for which approval was sought;

c. the date the application was made;

d. the percentage of the crop for which the application was made which contained aflatoxin at levels in excess of 20 ppb;

e. what action the FDA took with respect to the application, and the reasons for such action; and

f. identify all documents which reflect, refer or relate to the information provided above, including, but not limited to, documents which reflect each application and the FDA's action in response to it.

ANSWERS

5. In 1978 (see 43 F.R. 14122) FDA established a limited exemption to its prohibition against blending corn containing aflatoxin above its 20 ppb action level with less contaminated corn to achieve a mixture below 20 ppb when the corn had not first been shipped in interstate commerce and was to be used only in certain animal feed. In 1980 (see 46 F.R. 7447), FDA agreed, if certain conditions were met, to not recommend regulatory action against corn which contains between 20 ppb and 100 ppb aflatoxin or which has been blended with corn containing in excess of 20 ppb to achieve a level of no more than 100 ppb aflatoxin if, *inter alia*, the corn is used only for feeding

mature, nonlactating livestock and mature poultry. To date, FDA has not received any applications, pursuant to the above exemptions, for permission to ship corn which contains aflatoxin at levels in excess of 20 ppb or which has been blended.

INTERROGATORY NO. 6

State whether blending has ever been approved for any food or other substance other than corn containing aflatoxin and, if so, identify all documents reflecting an application for blending authority and FDA's approval.

ANSWER

6. FDA has stated that it would not recommend regulatory action against lots of corn containing aflatoxin which had blended under certain conditions. (See 43 F.R. 14122; 46 F.R. 7447). FDA has never approved blending for any other food or any other substance.

INTERROGATORY NO. 7

Describe the amount of aflatoxin which remains in the tissue of mature, non-lactating animals which are fed corn containing a) 20 ppb aflatoxin, and b) 100 ppb aflatoxin. c) Identify all documents, articles, or other materials relied on to support the figures cited. d) Identify all documents, articles or other materials which dispute or disagree with the figures cited.

ANSWER

7. a) No detectable amount of aflatoxin remains in the tissues of mature, non-lactating animals which are fed corn containing 20 ppb aflatoxin and FDA therefore does not know what amount, if any, is present in the tissue of said animals.

b) No detectable amount of aflatoxin remains in the tissue of mature, non-lactating animals which are fed corn containing 100 ppb aflatoxin and FDA therefore does not know what amount, if any, is present in the tissue of said animals. As explained at page 6 of the "Aflatoxin-Contaminated Corn limited exemptions from prohibition of interstate shipment and blending—Assessments of Safety and Impact on the Nation Food Supply," Food and Drug Administration, December 1980, (Assessment) (Attached as Exhibit 2) an 800:1 feed tissue ration for swine does indicate that residues might be detected in swine liver when aflatoxin levels exceed 80 ppb in the animal's total ration. However, because corn is usually fed with other ingredients, the aflatoxin levels in the total swine ration will be lower than in the corn alone. Accordingly, aflatoxin residues in the liver from the total ration are not expected to exceed the 0.1 ppb level of detection.

c) The documents, articles, or other materials relied on to support the answers to 7a and 7b above are referred to in the Assessment, references 1-16.

d) Defendant is unaware of any documents, d) Defendant is unaware of any documents, articles, or other materials which dispute or disagree with the figures cited in 7a and 7b above.

INTERROGATORY NO. 8

Identify any regulation which establishes the method of examination approved by the Secretary of Health and

Human Services or other person for measuring the amount of aflatoxin which is found in the tissues of livestock or poultry fed aflatoxin-contaminated corn.

ANSWER

8. No such regulation has been established by the Secretary or any other person in the Department of Health and Human Services.

INTERROGATORY NO. 9

a) Identify all documents, articles, or other materials which support FDA's conclusion that corn containing up to 100 ppb aflatoxin can be safely fed to mature, non-lactating livestock and poultry, with no significant risk to human consumption of the animals fed such corn. b) Identify all documents, articles, or other materials which dispute or negate the conclusion that corn containing up to 100 ppb aflatoxin can safely be fed to mature, non-lactating livestock or poultry, with no significant risk to human consumption of the animals fed such corn. c) Explain the basis for FDA's conclusion that corn containing up to 100 ppb aflatoxin cannot be approved for feed for young or lactating animals or for human consumption.

ANSWER

9. a) See answer 7c for documents relied on by FDA. Other documents, articles or other materials which support FDA's conclusion that corn containing up to 100 ppb Aflatoxin can be safely fed to mature, non-lactating livestock and poultry with no significant risk to humans who consume animals fed such corn exist, but FDA objects to having to provide such a list on the ground that it is unduly burdensome for FDA to locate *all*

documents, articles, or other materials which support its position, especially when the documents relied on by FDA are available for public inspection at the FDA Documents Management Branch.

b) Defendant is unaware of any documents, articles or other materials which dispute or negate the above conclusion.

c) The basis for FDA's conclusion that corn containing up to 100 ppb Aflatoxin cannot be approved for feed for young or lactating animals or for human consumption is explained in the Assessment, pp. 4-7.

INTERROGATORY NO. 10

Explain the basis for FDA's establishment of a 20 ppb action level for aflatoxin-contamination in corn.

ANSWERS

10. Aflatoxin is a toxic chemical compound produced by the common molds aspergillus flavus. The initial action level for aflatoxin in foods (including corn) was set at 30 ppb in 1965. This level was subsequently lowered to 20 ppb in 1969. At the time they were established, the basis for these action levels was the lowest level at which the presence of aflatoxin could be demonstrated with sufficient certainty to support a court action, using prevailing practical analytical methology. See also a paper entitled, "*Aflatoxin Control: Past and Present*," presented by Mr. Leonard Stoloff of the United States Food and Drug Administration at a symposium on "Toxicity and Food Safety" at the ISF-AOCS World Congress, New York, N.Y., April 28, 1980 (attached as Exhibit 3).

INTERROGATORY No. 11

Identify the statutory basis for 21 C.F.R. § 509.8(a)(1), which permits an exemption from regulatory action when the Commissioner finds that destruction of a food would result in substantial adverse impact on the food supply.

ANSWER

The Federal Food, Drug, and Cosmetic Act, Sections 306, 402, 406, and 701, 21 U.S.C. 336, 342, 346 and 371.

INTERROGATORY NO. 12

Identify all documents which relate to or formed the basis for FDA's statement in 1978 that "permitting corn containing up to 100 ppb aflatoxin to be shipped in interstate commerce would present an unreasonable risk that the corn would be used for food for human consumption." 43 F.R. 14123 (April 4, 1978).

ANSWER

12. No particular document or set of documents formed the basis for the statement quoted in Interrogatory No. 12. That statement was based upon two factors: FDA's belief that it did not have the resources to adequately monitor and control interstate shipments of corn to assure that no corn containing in excess of 20 ppb would not be diverted for use for feed for young animals, dairy animals, or for human food; and the States' representations to FDA that they could not monitor the corn closely enough to ensure that the limitation was adhered to. The FDA has located the following documents which relate to the statement by FDA quoted in Interrogatory No. 12:

i) August 30, 1977 telegram from Donald Kennedy, Commissioner, FDA to Tommy Irvin, State of Georgia.
ii) September 1, 1977 FDA Talk Paper, "Aflatoxin in Corn."

i) September 7, 1977 telegram from G. Bryan Patrick, State of South Carolina to Taylor Quinn, FDA.
iv) September 8, 1977 telegram from Taylor Quinn, FDA to G. Bryan Patrick, State of South Carolina.
v) September 9, 1977 telegram from Taylor Quinn, FDA to C. J. Sullivan, State of Alabama.
vi) September 9, 1977 telegram from Taylor Quinn, FDA to James A. Graham, State of North Carolina.
vii September 23, 1977 telegram from Glenn W. Kilpatrick, FDA to Robert M. Reeves, State of Tennessee.
viii October 5, 1977 letter from Howard R. Roberts, FDA to W. E. McDomel, State of Delaware.
ix) October 14, 1977, FDA Talk Paper, "Aflatoxin in Southeast: General Update."
x) November 3, 1977 letter from Donald Kennedy, Commissioner, FDA to W. Y. Cobb, State of North Carolina.

INTERROGATORY NO. 13

a) Explain the basis for FDA's conclusion that, contrary to its determination in 1978, the interstate shipment of corn containing up to 100 ppb aflatoxin would no pose a risk of use for human consumption in 1980, and explain why the factors relied on to reach this conclusion were not present in 1978. b) Identify all documents which dispute, support, or are in any way relevant to the issue of whether the interstate shipment of corn containing up to 100 ppb aflatoxin would pose a risk that the corn would be used for human consumption.

ANSWER

13. a) As stated in the Federal Register of January 23, 1981 (46 FR 7447) the FDA did not permit corn

containing more than 20 ppb aflatoxin to be shipped in interstate commerce in 1978 because "some states have told FDA that they cannot monitor the use of the corn closely enough to ensure that the limitation is adhered to" and "because FDA cannot monitor the flow of corn in interstate commerce to the extent necessary to ensure that the corn is used in accordance with the terms of the exemption." In 1980, the States of North and South Carolina and the Commonwealth of Virginia submitted to FDA detailed control plans to ensure that corn containing up to 100 ppb aflatoxin when shipped in interstate commerce is not diverted for uses other than as feed for mature, non-lacting livestock and mature poultry (46 F.R. at 7447-7448). These control plans were not submitted to FDA in 1978 and therefore FDA decided to allow only corn containing up to 20 ppb aflatoxin to be shipped in interstate commerce.

i) August 28, 1980 letter from Mr. G. Bryan Patrick, State of South Carolina to Mr. Joseph P. Hile, FDA.
ii) September 12, 1980 telegram from Joseph P. Hile, FDA to Mr. G. Bryan Patrick, Jr., State of South Carolina.
iii) August 29, 1980 letter from James A. Graham, State of North Carolina to Mr. Joseph P. Hile, FDA.
iv) September 9, 1980 mailgram from Mr. James A. Graham, State of North Carolina to Mr. J. P. Hile, FDA.
v) September 12, 1980 telegram from Joseph P. Hile, FDA to James A. Graham, State of North Carolina.

vi) September 18, 1980 telegram from James A. Graham, State of North Carolina to J. P. Hile, FDA.
vii) September 19, 1980 letter from Bryan Patrick, State of South Carolina, to Mr. Joseph P. Hile, FDA.
viii) October 10, 1980 letter from James A. Graham, State of North Carolina to Mr. J. P. Hile, FDA.
ix) October 8, 1980 telegram from Joseph P. Hile, FDA to G. Bryan Patrick, Jr., State of South Caroiina.
x) September 19, 1980 letter from James A. Graham, State of North Carolina to Mr. J. P. Hile, FDA.
xi) September 25, 1980 memorandum of meeting, subject—aflatoxin in 1980 corn crop.
xii) October 8, 1980 telegram from Joseph P. Hile, FDA to James A. Graham, State of North Carolina.
xiii) October 9, 1980 telegram from North Carolina Department of Agriculture Commissioner James A. Graham to J. P. Hile, FDA.
xiv) October 28, 1980 letter from Commonwealth of Virginia to Mr. Joseph P. Hile.
xv) October 17, 1980 telegram from Mr. Joseph P. Hile, FDA to the States of Texas. Oklahoma, Arkansas, Louisiana, Mississippi, Alabama, Tennessee, Kentucky, Georgia, Florida, South Carolina, North Carolina, Virginia, Maryland and Delaware.
xvi) October 29, 1980 telegram from Mr. Joseph P. Hile, FDA to Mr. S. Mason Carbaugh, Commonwealth of Virginia.
xvii) October 31, 1980 letter to Mr. S. Mason Carbaugh from Taylor M. Quinn, FDA.

xviii) November 5, 1980 telegram from Associate Commissioner for Regulatory Affairs, FDA to S. Mason Carbaugh, Commonwealth of Virginia.

xix) November 5, 1980 telegram from Associate Commissioner for Regulatory Affairs, FDA to G. Bryan Patrick, Jr., State of South Carolina.

xx) November 5, 1980 telegram from Associate Commissioner for Regulatory Affairs, FDA to James A. Graham, State of North Carolina.

INTERROGATORY NO. 14

State whether FDA viewed the aflatoxin contamination of the corn crop in the southeastern portion of the United States to be more severe in 1980 than in 1978 and, a) if so, describe the basis for this conclusion, b) if not, state why FDA approved the shipment of corn containing up to 100 ppb aflatoxin in 1980, but not in 1978.

ANSWER

14. a) As stated in the Federal Register of January 23, 1981 (46 FR 7447), "Analyses of samples of the 1980 corn crop from the States of North Carolina and South Carolina and the Commonwealth of Virginia reveal that aflatoxin contamination in those states is at least as great as, if not greater than, the aflatoxin contamination in the 1977 corn crop harvested in parts of the southeast United States. North Carolina, South Carolina, and Virginia, estimate that 63, 73 and up to 23 percent of their 1980 corn crop, respectively, may contain more than 20 ppb aflatoxin." Also, data from other Southeastern states indicates there may be a problem with aflatoxin contamination of 1980 harvested corn for the entire region which may result in requests from other states for similar exemptions. (See Assessment, p. 9).

INTERROGATORY NO. 15

Describe what monitoring actions FDA has taken to determine whether corn containing aflatoxin in excess of 20 ppb is being diverted to uses designed for human consumption.

ANSWER

15. No requests for the interstate shipment of corn containing aflatoxin in excess of 20 ppb have been received under the limited exemptions notice (see the Federal Register of January 23, 1981 (46 F.R. 7447)); therefore no monitoring of such blending or interstate shipment has taken place. FDA District Offices have continued normal surveillance and compliance activities with respect to corn products in conjunction with the surveillance and compliance activities of and, with the various states involved, will monitor and enforce compliance with the exemptions.

INTERROGATORY NO. 16

State whether the states of North Carolina, South Carolina and Virginia have, since 1978, acquired improved enforcement and monitoring capabilities to assure that corn containing up to 100 ppb aflatoxin is not used for human consumption, and identify all documents which relate or refer to this issue.

ANSWER

16. Yes. See Answer to Interrogatory No. 13, the Federal Register of January 23, 1981, (46 F.R. 7448-49) and the following documents on file with the Dockets Management Branch, at 80N-0520, Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857:

i) September 19, 1980 letter from Bryan Patrick, State of South Carolina, to Mr. Joseph P. Hile, FDA.
ii) October 8, 1980 telegram from Joseph P. Hile, FDA to G. Bryan Patrick, Jr., State of South Carolina.
iii) September 19, 1980 letter from James A. Graham, State of North Carolina to Mr. J. P. Hile, FDA.
iv) October 8, 1980 telegram from Joseph P. Hile, FDA to James A. Graham, State of North Carolina.
v) October 28, 1980 letter from Commonwealth of Virginia to Mr. Joseph P. Hile.
vi) November 5, 1980 telegram from Associate Commissioner for Regulatory Affairs, FDA to S. Mason Carbaugh, Commonwealth of Virginia.
vii) October 24, 1980 letter from John Bass, State of South Carolina to Taylor Quinn, FDA.
viii) October 21, 1980 letter from Bryan Patrick, State of South Carolina to unaddressed.
ix) October 22, 1980 Memorandum from John A. Bass, State of South Carolina to Bill Whitely, Truluck Kelly, and C. T. Smith.
x) October 21, 1980 letter from Bryan Patrick, State of South Carolina to South Carolina Grain dealers.
xi) November 5, 1980 telegram from Associate Commissioner for Regulatory Affairs, FDA to G. Bryan Patrick, Jr., State of South Carolina.
xii) October 10, 1980 letter from James A. Graham, State of North Carolina to Mr. J. P. Hile, FDA.

xiii) November 5, 1980 telegram from Associate Commissioner for Regulatory Affairs, FDA to James A. Graham, State of North Carolina.
xiv) January 28, 1981 memorandum from Richard Moats, FDA to HFO-1.
xv) January 30, 1981 memorandum from Richard Moats, FDA to Acting Executive Director of Regional Operations, FDA.
xvi) February 2, 1981 telegram from Leonard F. Blanton, State of North Carolina to Richard Moats, FDA.
xvii) February 6, 1981 letter from A. D. Dell'Aria, Commonwealth of Virginia to Gentlemen.
xviii) February 6, 1981 inter-office Correspondence from Paul Ferrara, State of South Carolina to Bill Southall.
xix) February 1, 1981 telegram from Truluck Kelly, State of South Carolina to Richard Moats, FDA.

INTERROGATORY NO. 17

a) Identify all states which could receive corn shipped from North Carolina, South Carolina and Virginia and state whether they have, since 1978, acquired improved enforcement and monitoring capabilities to assure that corn containing up to 100 ppb aflatoxin is not used for human consumption. b) Identify all documents which refer or relate to this issue.

ANSWER

17. a) Any of the 49 other states "could" receive corn shipped from North Carolina, South Carolina and Virginia. Defendant is without knowledge to answer the second part of 17a but can state that the States of North Carolina, South

Carolina, and the Commonwealth of Virginia submitted control plans in 1980 which were not submitted in 1978 and which require states receiving corn from these states to comply with certain requirements to protect against unauthorized diversion of corn containing in excess of 20 ppb in order to receive corn shipped in interstate commerce pursuant to these exemptions.

b) See Answer 16.

INTERROGATORY NO. 18

List, describe and give the date of all instances of known or suspected violations of FDA's action levels and other policies regulating the interstate shipment of corn which have occurred since September, 1979.

ANSWER

18. The following list describes all instances of known or suspected violations of FDA's action levels and other policies regulating the interstate shipment of corn containing aflatoxin which have occurred since September, 1979. In many cases the corn from which these samples were collected had not moved in interstate commerce and therefore was outside of FDA's jurisdiction.

Corn Samples Collected and Found to Contain Aflatoxin Levels Above 20 ppb

Shelled Corn

Sample Number	*Collecting District*	*Collection Date*
0228859	Atlanta	9/22/80
0104654	Baltimore	9/5/80
0210319	Dallas	11/20/79
0222479	Houston	5/14/80
0221222	New Orleans	11/6/79
0221225	New Orleans	11/6/79
0228856	Nashville	9/15/80
0228857	Nashville	9/15/80
0228858	Nashville	9/15/80
0229467	Nashville	9/18/80
0229468	Nashville	9/18/80
0229469	Nashville	9/18/80
0229470	Nashville	9/18/80
0229471	Nashville	9/18/80
0229472	Nashville	9/18/80
0235750	Nashville	9/19/80
0235751	Nashville	9/19/80
0235752	Nashville	9/19/80
0268104	Orlando	9/17/80
0268106	Orlando	9/24/80
0268107	Orlando	9/24/80
0268108	Orlando	9/24/80
0268109	Orlando	9/24/80
0268110	Orlando	9/24/80
0268111	Orlando	9/24/80
0167226	Orlando	12/13/79
FY 81 To Date		
81163873	Atlanta	11/5/80
81260882	Houston	10/31/80
81237341	Atlanta	11/17/80

FY 81 To Date

Sample Number	*Collecting District*	*Collection Date*
81206575	Baltimore	10/8/80
81206579	Baltimore	10/16/80
81260034	Houston	10/28/80
81181511	Houston	12/16/80
81122136	New Orleans	11/18/80
81229482	Nashville	11/25/80
81235359	Nashville	11/19/80
81275624	Nashville	11/19/80
81223660	Philadelphia	10/14/80
81235658	Nashville	12/22/80
81235738	Nashville	11/4/80
81235377	Nashville	11/21/80
81275632	Nashville	12/16/80
81230296	Atlanta	1/19/81

Corn, Meal or Ground

FY 80

0221223	New Orleans	11/06/79
0230085	Atlanta	9/9/80
0230083	Atlanta	9/9/80
0238681	Atlanta	2/1/80
0238575	Atlanta	1/29/80

FY 81 To date

81163874	Atlanta	11/5/80
81236840	Atlanta	10/31/80
81237342	Atlanta	11/17/80
81237344	Atlanta	11/25/80
81163874	Atlanta	11/5/80
81236839	Atlanta	10/31/80
81248084	Chicago	10/16/80

City of Washington)
) ss
District of Columbia)

Taylor Quinn, being first duly sworn, deposes and says that he is Associate Director for Compliance, Bureau of Foods, United States Food and Drug Administration, Rockville, Maryland; that in such capacity he answers the above interrogatories, and, that the answers are to his best knowledge and belief true, although the truth of each of said answer is not known to him personally.

/s/
TAYLOR QUINN

Subscribed and sworn to before me this 6th day of March, 1981, in the City and District aforesaid.

/s/
NOTARY PUBLIC

My commission expires:
August 31, 1981

EXHIBIT 1

ACTION LEVELS FOR POISONOUS OR DELETERIOUS SUBSTANCES IN HUMAN FOOD AND ANIMAL FEED

Action levels for poisonous or deleterious substances are established by the Food and Drug Administration (FDA) to control levels of contaminants in human food and animal feed.

The action levels are established and revised according to criteria specified in Title 21, *Code of Federal Regulations*, Parts 109 and 509 and are revoked when a regulation establishing a tolerance for the same substance and use becomes effective.

Action levels and tolerances represent limits at or above which FDA will take legal action to remove adulterated products from the market. Where no established action level or tolerance exists, FDA may take legal action against the product at the minimal detectable level of the contaminant.

Action levels and tolerances are established based on the unavoidability of the poisonous or deleterious substance and do not represent permissible levels of contaminations, where it is avoidable. The blending of a food or feed containing a substance in excess of an action level or tolerance with another food or feed is not permitted, and the final product resulting from blending is unlawful, regardless of the level of the contaminant.

This booklet lists action levels established by the FDA for poisonous or deleterious substances in human food and animal feed. The list is current as of July, 1980. Notices will be published in the *Federal Register* as new action levels are established or as existing action levels are revised or revoked. It is the responsibility of the user of the list to keep up to date on changes in the action levels.

Single copies of this list are available from:

Food and Drug Administration
Industry Programs Branch
Bureau of Foods (HFF-326)
200 C Streets, S.W.
Washington, D.C. 20204
Phone (202) 245-1523

FDA ACTION LEVELS

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*Indicates revisions since September 1, 1979.

AFLATOXIN

Commodity	*Action Level*	*Reference*
Brazil nuts	20.0 mcgs/kg	AG 7412.01
Foods and feeds	20.0 mcgs/kg	AG 7420.01
Milk	0.5 mcgs/kg (aflatoxin M_1)	AG 7406.06
Peanuts & peanut products	20.0 mcgs/kg	AG 7412.03
Pistachio nuts	20.0 mcgs/kg	AG 7412.05

ALDRIN & DIELDRIN

The figures below are for residues of the above pesticides individually or in combination. However, in adding amounts of aldrin and dieldrin do not count aldrin or dieldrin found at a level below 0.3 ppm for nonfatty foods and 0.3 ppm for fish and for milk.

ALDRIN & DIELDRIN—Continued

Commodity	*Action Level*	*Reference*
Animal feed, processed	0.03 ppm	AG 7426.04-A
Artichokes	0.05 ppm	AG 7420.08-A
Eggs	0.03 ppm	AG 7420.08-A
Fats & oils: animal, vegetable fish (animal feed)	0.3 ppm	AG 7426.04-A
Fish and shellfish	0.3 ppm	AG 7420.08-A
Pigs	0.05 ppm	AG 7420.08-A
Hay (animal feed)	0.03 ppm	AG 7426.04-A
Melons[1]	0.15 ppm	AG 7420.08-A
Milk and dairy products	0.3 ppm (fat basis)	AG 7420.08-A
Small fruits[1,2]	0.05 ppm	AG 7420.08-A
Sugarbeet pulp (animal feed)	0.1 ppm	AG 7426.04-A

[1]Other than those commodities specified in 40 CFR 180.135 and 180.137.

[2]Refer to 40 CFR 180.34(f) for commodities covered by this food group.

BENZENE HEXACHLORIDE (BHC)

The figures below are for residues of total BHC. However, in adding amounts of individual isomers do not count alpha, gamma or delta BHC at a level below 0.1 ppm in milk or eggs and below 0.02 in other products. Do not count beta BHC at a level below 0.2 in milk or eggs and below 0.04 in other products.

Commodity	*Action Level*	*Reference*
Animal feed, processed	0.1 ppm	AG 7426.04-B
Barley, grain (animal feed)	0.1 ppm	AG 7226.04-B
Barley, grain (human food)	0.1 ppm	AG 7420.08-B
Beans	0.5 ppm	AG 7420.08-B
Citrus fruit[2]	0.5 ppm	AG 7420.08-B
Cocoa beans, whole raw bean	0.5 ppm	AG 7420.08-B
Corn, fresh sweet	0.5 ppm	AG 7420.08-B
Corn, grain (animal feed)	0.1 ppm	AG 7426.04-B
Corn, grain (human food)	0.1 ppm	AG 7420.08-B
Eggs	0.5 ppm	AG 7420.08-B
Endive	0.5 ppm	AG 7420.08-B
Figs	0.5 ppm	AG 7420.08-B
Frog legs	0.5 ppm	AG 7420.08-B

BENZENE HEXACHLORIDE (BHC)—Continued

Commodity	*Action Level*	*Reference*
Guavas	0.5 ppm	AG 7420.08-B
Hays (animal feed)	0.1 ppm	AG 7426.04-B
Mangoes	0.5 ppm	AG 7420.08-B
Milk and dairy products	0.3 ppm (fat basis)	AG 7420.08-B
Milo, sorghums (animal feed)	0.1 ppm	AG 7426.04-B
Milo, sorghums (human food)	0.1 ppm	AG 7420.08-B
Oats, grain (animal feed)	0.1 ppm	AG 7426.04-B
Oats, grain (human food)	0.1 ppm	AG 7420.08-B
Peas	0.5 ppm	AG 7420.08-B
Pineapples	0.5 ppm	AG 7420.08-B
Quinces	0.5 ppm	AG 7420.08-B
Root vegetables[2]	0.5 ppm	AG 7420.08-B
Rice, grain	0.1 ppm	AG 7420.08-B
Rye, grain (animal feed)	0.1 ppm	AG 7426.04-B
Rye, grain (human food)	0.1 ppm	AG 7420.08-B

BENZENE HEXACHLORIDE (BHC)—Continued		
Commodity	*Action Level*	*Reference*
Small fruits[1, 2]	0.5 ppm	AG 7420.08-B
Turnip greens	0.5 ppm	AG 7420.08-B
Wheat, grain (animal feed)	0.1 ppm	AG 7426.04-B
Wheat, grain (human food)	0.1 ppm	AG 7420.08-B

[1]Other than those commodities specified in 40 CFR 180.146.
[2]Refer to 40 CFR 180.34(f) for commodities covered by this food group.

CADMIUM		
Commodity	*Action Level*	*Reference*
Pottery (ceramics) Flatware (ave. of 6 units)	0.5 mcgs/ml of leaching solution	AG 7417.02
Small holloware (any one of 6 units)	0.5 mcgs/ml of leaching solution	AG 7417.02
Large holloware (any one of 6 units)	0.25 mcgs/ml of leaching solution	AG 7417.02

CHLORDANE		
Commodity	*Action Level*	*Reference*
Animal fat, rendered	0.8 ppm	AG 7426.04-D
Animal feed, processed	0.1 ppm	AG 7426.04-D
Fish	0.3 ppm	AG 7420.08-L

CROTOLARIA SEEDS (C. spectabilis and/or C. striata)		
Commodity	*Action Level*	*Reference*
Grains and Feeds	Average of 1 whole seed/pound	AG 7426.03

DIBROMOCHLOROPROPANE		
Commodity	*Action Level*	*Reference*
Milk, raw, unpasteurized	1.5 ppm (fat basis)	AG 7420.08
Raw agricultural commodities (except milk)	0.05 ppm	AG 7420.08

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DDT, DDE, AND TDE

The figures below are for residues of the above pesticides individually or in combination. However, in adding amounts of DDT, DDE and TDE do not count any of the three found below 0.2 ppm for fish, eggs, and grain.

Commodity	*Action Level*	*Reference*
Animal feed, processed	0.5 ppm	AG 7426.04-
Barley, grain (animal feed)	0.5 ppm	AG 7426.04-
Barley, grain (human food)	0.5 ppm	AG 7420.08-

DDT, DDE, AND TDE—Continued

Commodity	*Action Level*	*Reference*
Cocoa beans, whole raw bean	2.0 ppm	AG 7420.08-
Corn, grain (animal feed)	0.5 ppm	AG 7426.04-
Corn, grain (human food)	0.5 ppm	AG 7420.08-
Eggs	1.5 ppm	AG 7420.08-
Fish	5.0 ppm	AG 7420.08-
Hay	0.5 ppm	AG 7426.04-
Milo (sorghum), grain (animal feed)	0.5 ppm	AG 7426.04-
Milo (sorghum), grain (human food)	0.5 ppm	AG 7420.08-
Oats, grain (animal feed)	0.5 ppm	AG 7426.04-
Oats, grain (human food)	0.5 ppm	AG 7420.08-
Rice, grain (animal feed)	0.5 ppm	AG 7426.04-
Rice, grain (human food)	0.5 ppm	AG 7420.08-
Rye, grain (animal feed)	0.5 ppm	AG 7426.04-
Rye, grain (human food)	0.5 ppm	AG 7420.08-
Wheat, grain (animal feed)	0.5 ppm	AG ???????
Wheat, grain (human food)	0.5 ppm	AG ????????

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ENDRIN		
Commodity	*Action Level*	*Reference*
Animal feed, processed	0.03 ppm	AG 7426.04-F
Asparagus	0.05 ppm	AG 7420.08-E
Beans	0.05 ppm	AG 7420.08-E
Citrus fruits[2]	0.05 ppm	AG 7420.08-E
Corn, fresh sweet	0.05 ppm	AG 7420.08-E
Eggs	0.03 ppm	AG 7420.08-E
Figs	0.05 ppm	AG 7420.08-E
Fish and shellfish	0.3 ppm	AG 7420.08-E
Fish meal, fish solubles, fish oil (animal feed)	0.3 ppm	AG 7426.04-F
Guavas	0.05 ppm	AG 7420.08-E
Leafy vegetables[1,2]	0.05 ppm	AG 7420.08-E
Mangoes	0.05 ppm	AG 7420.08-E
Melons	0.05 ppm	AG 7420.08-E
Milk and dairy products	0.3 ppm (fat basis)	AG 7420.08-E
Oilseed meal, peanut, soybean, cottonseed, etc. (animal feed)	0.03 ppm	AG 7426.04-F

ENDRIN—Continued		
Commodity	*Action Level*	*Reference*
Okra	0.05 ppm	AG 7420.08-E
Peas	0.05 ppm	AG 7420.08-E
Pimentoes	0.05 ppm	AG 7420.08-E
Pineapples	0.05 ppm	AG 7420.08-E
Pome fruits[2]	0.05 ppm	AG 7420.08-E
Pumpkins	0.05 ppm	AG 7420.08-E
Root vegetables[1,2]	0.05 ppm	AG 7420.08-E
Small fruits[2]	0.05 ppm	AG 7420.08-E
Stone fruits[2]	0.05 ppm	AG 7420.08-E
Vegetable oils and fats, including soapstock (animal feed)	0.3 ppm	AG 7426.04-F

[1]Other than those commodities specified in 40 CFR 180.131.
[2]Refer to 40 CFR 180.34(f) for commodities covered by this food group.

FENTHION		
Commodity	*Action Level*	*Reference*
Ground red peppers	0.3 ppm	AG 7420.08-F

HEPTACHLOR AND HEPTACHLOR EPOXIDE		
Commodity	*Action Level*	*Reference*
Animal feed, processed	0.03 ppm	AG 7426.04-G
Artichokes	0.05 ppm	AG 7420.08-G
Asparagus	0.05 ppm	AG 7420.08-G
Beans, except snap beans	0.05 ppm	AG 7420.08-G
Citrus fruits[2]	0.05 ppm	AG 7420.08-G
Cucumbers	0.05 ppm	AG 7420.08-G
Dairy products (manufactured) except low fat dairy products[1]	0.3 ppm	AG 7420.08-G
Eggs	0.03 ppm	AG 7420.08-G
Eggplant	0.05 ppm	AG 7420.08-G
Figs	0.05 ppm	AG 7420.08-G
Fish and shellfish	0.3 ppm	AG 7420.08-G
Leafy vegetables	0.05 ppm	AG 7420.08-G

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HEPTACHLOR AND HEPTACHLOR EPOXIDE – Continued		
Commodity	*Action Level*	*Reference*
Hays[1]	0.03 ppm	AG 7426.04-G
Melons	0.05 ppm	AG 7420.08-G
Okra	0.05 ppm	AG 7420.08-G
Pears	0.05 ppm	AG 7420.08-G
Pimentoes	0.05 ppm	AG 7420.08-G
Pumpkins	0.05 ppm	AG 7420.08-G
Quinces	0.05 ppm	AG 7420.08-G
Rice, grain, (animal feed)	0.03 ppm	AG 7426.04-G
Rice, grain (human food)	0.03 ppm	AG 7420.08-G
Small fruits[1, 2]	0.05 ppm	AG 7420.08-G
Stone fruits[1, 2]	0.05 ppm	AG 7420.08-G
Squash (summer or winter)	0.05 ppm	AG 7420.08-G

[1] Other than those commodities specified in 40 CFR 180.104 and 180.319.
[2] Refer to 40 CFR 180.34(f) for commodities covered by this food group.

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KELTHANE [1,1 Bis (p-chlorophenyl)-2,2,2,-trichloroethanol]		
Commodity	*Action Level*	*Reference*
Animal feed, processed	0.5 ppm	AG 7426.04-H

KEPONE [Decachlorooctahydro-1,3,4-methano-2H-cyclobuta (cd) pentalen-2-one]		
Commodity	*Action Level*	*Reference*
Crabmeat	0.4 ppm	AG 7420.08-H
Fish	0.3 ppm	AG 7420.08-H
Shellfish	0.3 ppm	AG 7420.08-H

LEAD		
Commodity	*Action Level*	*Reference*
Pottery (ceramics) Flatware (ave. of 6 units)	0.7 mcgs/ml of leaching solution	AG 7417.03
Small holloware (any one of 6 units)	5.0 mcgs/ml of leaching solution	AG 7417.03

LEAD – Continued		
Commodity	*Action Level*	*Reference*
Large holloware (any one of 6 units)	2.5 mcgs/ml of leaching solution	AG 7417.03
Silver-plated hollowware (ave. of 6 units)	7.0 mcgs/ml of leaching solution if product intended for use by adults	AG 7417.01
Silver-plated hollowware (one or more of 6 units)	0.5 mcgs/ml of leaching solution if product intended for use by infants and children	AG 7417.01

LINDANE		
Commodity	*Action Level*	*Reference*
Animal feed, processed	0.1 ppm	AG 7426.04-I
Artichokes	0.5 ppm	AG 7420.08-I
Barley (animal feed)	0.1 ppm	AG 7426.04-I
Barley (human food)	0.1 ppm	AG 7420.08-I
Beans	0.5 ppm	AG 7420.08-I
Citrus fruits[2]	0.5 ppm	AG 7420.08-I

LINDANE – Continued		
Commodity	*Action Level*	*Reference*
Cocoa beans, whole raw bean	0.5 ppm	AG 7420.08-I
Corn, fresh sweet	0.5 ppm	AG 7420.08-I
Corn, grain (animal feed)	0.1 ppm	AG 7426.04-I
Corn, grain (human food)	0.1 ppm	AG 7420.08-I
Eggs	0.5 ppm	AG 7420.08-I
Endive	0.5 ppm	AG 7420.08-I
Figs	0.5 ppm	AG 7426.08-I
Hays	0.1 ppm	AG 7426.04-I
Milk and dairy products	0.3 ppm (fat basis)	AG 7420.08-B
Milo (sorghum), grain (animal feed)	0.1 ppm	AG 7420.04-I
Milo (sorghum), grain, (human food)	0.1 ppm	AG 7420.08-I
Oats, grain (animal feed)	0.1 ppm	AG 7420 04-I
Oats, grain (human food)	0.1 ppm	AG 7420.08-I
Peas	0.5 ppm	AG 7420.08-I
Rice, grain (animal feed)	0.1 ppm	AG 7426.04-I
Rice, grain (human food)	0.1 ppm	AG 7426.08-I
Root vegetables[1, 2]	0.5 ppm	AG 7420.08-I
Rye, grain (animal feed)	0.1 ppm	AG 7426.04-I

LINDANE – Continued		
Commodity	*Action Level*	*Reference*
Rye, grain (human food)	0.1 ppm	AG 7420.08-I
Small fruits[1, 2]	0.5 ppm	AG 7420.08-I
Turnip greens	0.5 ppm	AG 7420.08-I
Wheat, grain (animal feed)	0.1 ppm	AG 7426.04-I
Wheat, grain (human food)	0.1 ppm	AG 7420.08-I

[1]Other than those commodities specified in 40 CFR 180.133.
[2]Refer to 40 CFR 180.34(f) for commodities covered by this food group.

MERCURY		
Commodity	*Action Level*	*Reference*
Fish, shellfish, crustaceans, other aquatic animals. Edible portion only. Fresh, frozen or processed	1.0 ppm	AG 7408.09
Wheat (pink kernals only)	1.0 ppm	AG 7404.04

METHYL ALCOHOL		
Commodity	*Action Level*	*Reference*
Imported brandy	0.35%	AG 7401.01

MIREX		
Commodity	*Action Level*	*Reference*
Fish	1.0 ppm	AG 7420.08-J

NITROSODIMETHYLAMINE (NDMA)		
Commodity	*Action Level*	*Reference*
Malt Beverages	.5 ppb	CPG 7101.06

PARALYTIC SHELLFISH TOXIN		
Commodity	*Action Level*	*Reference*
Claims (fresh, frozen, canned)	80 ug/100 g meat	AG 7408.04
Mussels (fresh, frozen, canned)	80 ug/100 g meat	AG 7408.04
Oysters (fresh, frozen, canned)	80 ug/100 g meat	AG 7408.04

POLYBROMINATED BIPHENYLS (PBB's)		
Commodity	*Action Level*	*Reference*
Milk & dairy product (fat basis)	0.3 ppm	"A Review of Congressman William M. Brodhead's Petition to Reduce FDA's Action Levels for Polybrominated Biphenyls (PBB) In Food", July 27
Meat (fat basis)	0.5 ppm	
Eggs	0.05 ppm	
Animal Feed	0.05 ppm	

POLYCHLORINATED BIPHENYLS (PCB's)		
Commodity	*Action Level*	*Reference*
Paper food-packaging material intended for or used with human food, finished animal feed & and components intended for animal feeds	10 ppm	21 CFR 109.30(a)(9) and 509.30(a)(9) Tolerance stayed on 8-24-73 (38 FR 22794) 21 CFR 109.6(d) and 509.6(d)
Red Meat	3 ppm (fat basis)	CPG 7111.02

TOXAPHENE		
Commodity	*Action Level*	*Reference*
Animal feed, processed	0.5 ppm	AG 7426.04-M
Artichokes	1.0 ppm	AG 7420.08-K
Asparagus	1.0 ppm	AG 7420.08-K
Cherries	1.0 ppm	AG 7420.08-K
Figs	1.0 ppm	AG 7420-08-K
Fish	5.0 ppm	AG 7420.08-K
Melons	1.0 ppm	AG 7420.08-K
Mustard greens	1.0 ppm	AG 7420.08-K
Plums	1.0 ppm	AG 7420.08-K
Pumpkins	1.0 ppm	AG 7420.08-K
Root vegetables[1, 2]	1.0 ppm	AG 7420.08-K
Small fruits[1, 2]	1.0 ppm	AG 7420.08-K
Squash (summer or winter)	1.0 ppm	AG 7420.08-K
Turnip greens	1.0 ppm	AG 7420.08-K

[1]Other than those commodities specified in 40 CFR 180.138.

[2]Refer to 40 CFR 180.34(f) for commodities covered by this food group.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 80-3110

COMMUNITY NUTRITION INSTITUTE, ET AL., PLAINTIFFS,

v.

ARTHUR HULL HAYES, JR., COMMISSIONER,
FOOD AND DRUG ADMINISTRATION, DEFENDANT.

STATEMENT OF MATERIAL FACTS AS TO WHICH THERE IS NO GENUINE DISPUTE

Pursuant to Rule 1-9(h) of the Rules of this Court, plaintiffs submit that there is no genuine issue as to the following material facts:

1. Aflatoxins are a group of chemically related substances produced by molds which can grow on corn and other agricultural products. Complaint ¶ 11; 39 F.R. 42748 (Dec. 6, 1974).

2. Aflatoxins are a potent liver carcinogen in laboratory animals. Complaint ¶ 11; 39 F.R. 42748 (Dec. 6, 1974).

3. There are epidemiological studies which report positive correlations between dietary aflatoxins and primary human liver cancer. Complaint ¶ 11; 39 F.R. 42748 (Dec. 6, 1974).

4. Since the 1960's, FDA has considered corn and other products contaminated in excess of certain amounts of aflatoxin to be adulterated within the meaning of the Food, Drug and Cosmetic (FDC") Act. Compaint ¶ 12.

5. In 1965, FDA established an action level for aflatoxin contamination in food at 30 parts per billion (ppb). 39 F.R. 42749 (Dec. 6, 1974).

6. In 1969, the action level was reduced to 20 ppb, which is the current action level for aflatoxin contamination in corn. Complaint ¶ 4; 39 F.R. 42749 (Dec. 6, 1974).

7. In January, 1978, FDA granted to the States of Alabama, Florida, Georgia, Mississippi, North Carolina, South Carolina and Virginia an exemption from 21 C.F.R. § 110.99(d), which prohibits the blending of adulterated with less contaminated corn. Plaintiffs' Exhibit 2. FDA did not publish a notice of this action until April 4, 1978. 43 F.R. 14122-14123.

8. In November, 1978, FDA granted to the States of North Carolina, South Carolina and Virginia another exemption from its prohibition on blending adulterated with less contaminated corn. Plaintiffs' Exhibits 3 and 4. At the same time, FDA granted an exemption from its 20 ppb action level by permitting the interstate shipment of corn containing up to 100 ppb aflatoxin, for use as feed for mature, non-lactating livestock and mature poultry. *Id.*

9. FDA granted the exemptions referred to in Paragraph 8 by way of telegrams to the Agricultural Departments of those three states. *Id.* It did not publish a notice until January 23, 1981. 48 F.R. 7447.

10. FDA has never established a formal tolerance level for aflatoxin contamination in corn, under section 406 of the FDC Act. Complaint ¶ 13.

11. Plaintiff Community Nutrition Institute ("CNI") is a non-profit public interest organization established to promote the formation of a sound food policy that serves the health needs of consumers at the community level. Compaint ¶ 4. CNI has long been active in opposing the sale of foods containing unsafe additives and other ingredients, and in a letter to FDA dated October 6, 1980, specifically opposed the FDA policies now challenged in this case. Complaint ¶ 4; Plaintiffs' Exhibit 1.

12. CNI is supported, in part, by annual contributions in the form of subscriptions from approximately 6,000 persons. Compaint ¶ 4. CNI brings this action on behalf of its supporters and also its approximately 28 employees, most or all of whom consume corn and related corn products, and milk and meat from animals which consume corn as feed, including corn containing aflatoxin. *Id.*

13. Plaintiff Public Citizen is a non-profit, public interest organization supported by annual contributions from approximately 40,000 persons. Complaint ¶ 5. Its Health Research Group ("HRG") is engaged in research and advocacy to promote safe food and drugs, and it has long opposed the sale of aflatoxin-contaminated food products. Public Citizen brings this action on behalf of its contributors and its approximately 52 employees, most or all of whom consume corn and related corn products, and milk and meat from animals fed on corn, including corn containing aflatoxin. *Id.*

14. Plaintiffs Linda S. Bardot and Laura A. Rogers are individuals who regularly eat corn and foods containing corn meal, and also drink milk and eat poultry, beef and pork, which come from animals fed on corn, including corn containing aflatoxin. Complaint ¶¶ 6-7.

Respectfully submitted,

/s/

Diane B. Cohn
William B. Schultz
Alan B. Morrison

Public Citizen Litigation Group
2000 P Street, N.W.,
Suite 700
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(202) 785-3704

Attorneys for Plaintiffs

March 10, 1982

EXHIBIT 2

Mr. Arthur Laramie
Louis Dreyfus Corporation
24 Richmond Hill Avenue
Stanford, Connecticut 06904

Dear Mr. Laramie:

This is in response to your letter of December 6, 1977, to Mr. Ceasar Roy, the director of the Division of Regulatory Guidance for FDA's Bureau of Foods, requesting that FDA permit 22,000 bushels of aflatoxin-contaminated corn located at your Pascagoula, Mississippi, grain elevator to be blended with uncontaminated corn and used for animal feed.

Corn which contains aflatoxin in excess of the established action level of 20 parts per billion (ppb) is an adulterated food under section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 342(a)(1). Use of an adulterated food as an ingredient in another food causes the finished food to be deemed to be adulterated, even if the finished product itself does not violate an established tolerance or action level. Tolerances and action levels for poisonous or deleterious substances such as aflatoxin apply only to unavoidable levels of contamination. Intentional blending of a violative article with an uncontaminated article is wholly avoidable and not authorized by such tolerances or action levels. Accordingly, the law does not permit you to blend adulterated corn with unadulterated corn as proposed in your letter.

Blending results in the redistribution rather than elimination of a contaminant. Since strict prohibition of blending helps eliminate from the food chain foods which contain contaminants at levels above the tolerance, consumer exposure to the contaminant is likely to be, on the average, at a level below the established tolerance. In

establishing tolerances, the degree of human exposure to the contaminant has been given consideration. If contaminated foods are permitted to enter the food chain by blending, the average exposure of the consumer will increase.

The observations of carcinogenic and other toxicologic effects of aflatoxin in animals and the positive correlations established between dietary aflatoxin and primary liver cancer in humans are of sufficient concern to warrant action to hold the human exposure to aflatoxins to the lowest practicable limit. The establishment of a tolerance is required to protect the public health and reduce human exposure to aflatoxins to be lowest practicable limit as determined by current technological capabilities to prevent or remove aflatoxin contamination of foods.

Since your letter asks about possibilities for use of the contaminated corn, we offer the following observations:

Export. Section 801(d)(1) of the FD&C Act permits export of an adulterated food if it:

(A) accords with the specifications of the foreign purchaser,

(B) is not in conflict with the laws of the country to which it is intended for export,

(C) is labeled on the outside of the shipping package that it is intended for export, and

(D) is not sold or offered for sale in domestic commerce.

FDA would not object to exportation of aflatoxin-contaminated corn in compliance with the conditions established by section 801(d)(1) of the act.

Note that, subject to the conditions of section 801(d)(1)(A) through (D), you *are* permitted to blend corn intended for export to produce a composite lot which meets the specifications of the foreign purchaser and is in accord with the laws of the country to which it is intended for export. Although the blending would cause the food to

be adulterated, if not intended for export, section 801(d)(1) exempts a food intended for export from adulterated status, subject to conditions (A) through (D).

Before export of corn which is adulterated because of aflatoxin contamination, pursuant to section 801(d)(1), you should procure documents specifically establishing that the level of contamination is acceptable to the foreign purchaser and is not in conflict with the laws of the country to which the corn is intended for export, and the documents should be kept in your permanent files. FDA will not hesitate to institute regulatory action (including criminal prosecutions) for export of aflatoxin-adulterated corn in violation of the conditions of section 801(d)(1).

Sale to *distillers or corn processors.* You may sell the contaminated corn for use by distillers or food processors if the use to be made of the corn will result in no aflatoxin in the finished product or products. Any aflatoxin-contaminated by-product, such as mash from distillation, would have to be disposed of for uses other than food or feed.

Special considerations arising out of 1977 southeastern harvest aflatoxin problem. We recognize that farmers and elevator operators in the southeastern United States face an unusual and economically-devastating problem with respect to aflatoxin contamination of the 1977 corn harvest. It appears that over half of the 1977 corn crop in the southeastern United States (Alabama, Florida, Georgia, Mississippi, North Carolina, South Carolina, and Virginia) may exceed the 20 ppb action level. (If contaminated corn is not introduced into interstate commerce, the local State law will govern use of the corn, assuming the corn is not used as an ingredient in food which is thereafter shipped in interstate commerce.)

Since it may be difficult for farmers in this area to find adequate supplies of corn for use in feeding animals if the law is enforced fully, the Commissioner has determined

that he will not recommend regulatory action for violation of the FD&C Act with respect to blending of such corn for use as animal feed if *all* of the following conditions are met:

(1) A technically feasible plan for blending must be provided, the plan to be approved by the FDA district office in Atlanta, Georgia, before blending operations commence. It must be demonstrated that the blending plan can reasonably be expected to result in a finished lot of corn containing less than 20 ppb of aflatoxin. the blending must be accomplished under Federal or State supervision, and the finished lot must be approved by Federal or State authorities before shipment in interstate commerce. It must be demonstrated to the satisfaction of the supervising Fed ral or State authority that the aflatoxin level of the blended lot is below 20 ppb.

(2) The aflatoxin-contaminated corn must not have been shipped in interstate commerce prior to FDA approval of the blending plan. (If FDA were to approve blending of corn after shipment in interstate commerce, there would be an unacceptable risk that some persons might ship contaminated corn in interstate commerce and blend only if the contaminated shipments were detected by Federal or State authorities. This condition should provide an incentive for farmers and elevator operators to treat corn for aflatoxin contamination *before* shipment in interstate commerce.)

(3) The blended lot must be offered for use only for animal feed for mature poultry, swine and beef animals other than milk-producing animals. (Aflatoxin is more likely to accumulate in the milk than in other tissues of animals consuming aflatoxin-contaminated corn and may harm young animals. The risk of undetected "pockets" of high aflatoxin

content corn within the blended lot is too great to authorize the use of blended corn for milk-producing or young animals.) Because aflatoxin is such a potent carcinogen, FDA will not under any circumstances authorize the blending for human consumption of corn exceeding the aflatoxin action level.

(4) This approval for limited blending applies only to corn harvested in the southeastern United States (Alabama, Florida, Georgia, Mississippi, North Carolina, South Carolina, and Virginia) during the 1977 harvest. But for the widespread presence of unavoidable aflatoxin contamination in this region during this harvest, resulting in acute regional shortages of feed corn containing aflatoxin below the usual action level, FDA would not tolerate any blending of aflatoxin-contaminated corn.

Although it appears to us that this exception policy with respect to blending is not applicable to the 22,000 bushels of corn at your Pascagoula, Mississippi, grain elevator (because that corn appears to have been shipped in interstate commerce), the above discussion concerning blending may be helpful with respect to other aflatoxin-contaminated lots.

Sincerely yours,

/s/

Donald Kennedy
Commissioner of Food and Drugs

cc: HF-1(2)
HF-2
HFF-1
GCF-1
HFC-1
HFO-1
HFF-310
HFI-1
HFL-1
HFF-300
HFO-300
HFC-20
HFV-1
HFC-13
Atlanta R.O. (Kinslow)
New York R.O.

Prepared by SMcNamara/mz: 1/11/78
Approved by: T. Quinn: 1/19/78
H. Roberts: 1/19/78
R. Cooper: GCF-1: 1/19/78
Initialed by: J. R. Wessel HFC-13 1/20/78
J. P. Hile HFC-1 1/20/78
S. Gardner 1/23/78
D. Kennedy 1/23/78

f/t:jjs:1-31-78

EXHIBIT 3

TELEGRAPHIC MESSAGE **ISSUED: 10/9/80**

To: G. Bryan Patrick, Jr., Commissioner, South Carolina Department of Argiculture

From: Joseph P. Hile, Associate Commissioner for Regulatory Affairs, Food and Drug Administration

Info: Atlanta District, HFR-4100

This responds to your letter of September 19, 1980 in which you submitted a proposed plan for controlling the interstate shipment of corn which will be certified by your agency as containing less than 100 ppb aflatoxin, in response to my September 12, 1980 telegram. Data which you submitted with your letter, indicates that approximately 73 percent of the 1980 South Carolina corn crop contains aflatoxin in excess of our administrative guideline of 20 ppb. We agree that an emergency situation exists and that special limited exemptions for the shipment in interstate commerce of corn exceeding the 20 ppb action level are necessary to prevent substantial adverse economic impact on the South Carolina farmers and the food supply, and to minimize the possibility of contaminated corn being used for human food or being fed to dairy animals.

We believe your proposed plan provides for adequate control mechanisms over such interstate shipments. We understand that your proposal was intended to be exactly like that of North Carolina's submission but that certain transcription errors resulted in apparent discrepancies. There are additionally certain items in your plan which require clarification and modification.

Item 4

References to analytical procedures should be more specific by stating that each sample will be analyzed by 13 AOAC 26.050–26.051. Each sample will be analyzed in duplicate and the average of the duplicate analyses used as the acceptance or rejection level.

Items 3 and 5

It appears that the word "screen" in the first sentence of item 3 should be "stream".

We agree that for nonblended lots the sampling procedure outlined in item 3; i.e., 1-10 lb sample per lot, is adequate if collected from ten locations. A rejection limit of 80 ppb will afford sufficient assurance that a lot containing a true mean of 100 ppb or more aflatoxin will be rejected at least 95 percent of the time. However, we believe that blended lots should be sampled more thoroughly to assure there was uniform mixing of the lot. For blended lots, two 10 pound samples should be drawn randomly from each lot following the procedures detailed in Item 3. Each 10 pound sample should be analyzed in duplicate. The average of the duplicate analyses of each two ten pound sample must not differ by more than 50 ppb (Two times the square root of two, times the standard error associated with the analytical and sampling errors), and the average of the four analyses must not exceed 80 ppb. If blending fails, reblending will be permitted.

Items 6 and 7

We agree with your proposed labeling except that the term "animals" should be replaced with the term "livestock." Because of the possible difficulty of maintaining an appropriate label on the "containers" of corn to be shipped, the bill of lading and other related documents (e.g., invoices) should also bear the aflatoxin content of

the lot and the phrase "to be fed only to nonlactating mature livestock or poultry." In Item 7, line 3, you state that records of "date sent" will be kept. You should also indicate on records the date the lot is sampled and also keep appropriate records documenting the integrity of the shipment to the receiving state (i.e., railcar seals, numbers of such seals, etc.). The bill of lading should also bear the seal numbers or other identification to relate it to the lot.

Item 8

We recognize that specific agreements with States receiving shipments may vary; however, we believe that all agreements should require written documentation from the ultimate user, stating that he agrees to feed the corn only to nonlactating mature livestock or poultry. The agreement should also identify the agency in the receiving state that will be responsible for monitoring the shipment to destination. Please submit copies of these agreements to the FDA Atlanta Regional office, attention Mr. Maurice Kinslow as soon as they are developed. If we have questions or concerns over their adequacy, the region will contact you immediately. Procedures for notification for individual shipments should be agreed upon by you and Atlanta region. These procedures must provide for special designation of blended lots.

Item 9

As stated in the meeting with Mr. Quinn on September 16, 1980, authorization for blending must be on a firm-by-firm basis. We request that you submit copies of each approved plan for blending to the FDA Atlanta Regional office. This will simplify our working with you on this program.

Item 11

It appears that the word "notification" should be "certification".

Page 3, paragraph 2

We cannot agree to this. Any interstate shipment of corn from South Carolina exceeding the 20 ppb action level may only be shipped under the auspices of this plan to which we have agreed. Any shipments made independent of this plan would, if found to exceed the 20 ppb action level, be considered adulterated and subject to condemnation. Thus, it is imperative that all potential corn shippers in your state be notified of this plan.

We ask that you revise your plan as outlined in this letter; also that you distribute your plan to your counterpart agencies in other states as well as to the other affected parties as you describe in Item 14.

FDA will periodically audit shipments made under this program to assist the states in assuring proper implementation of this program. We will do our utmost to expedite our response to any requests you make relative to this problem.

/s/

Joseph P. Hile

cc: HFC-1;HFC-2;HFC-6;HFC-20
HFR-41
HFR-4100
HFO-500
HFO-20
HFO-30
HFF-1
HFF-300
HFF-310
HFF-314(Phillips, r/f)
HFF-454(Stoloff)
HFV-200
HFV-230
HFL-1
HFF-300 r/f
R/D: F A Phillips: jn:10/2/80
Init: T M Quinn: 10/2/80
Concurred: R Moats: 10/3/80
G White: 10/3/80
E Ballitch: 10/3/80
C E. Coker: 10/6/80
RT:wcm: 10/7/80
Concur: E Ballitch: HFV-230: 10/7/80
S Terman: GCF-1: 10/7/80
A Celeste: HFO-20: 10/7/80
T Quinn: HFF-300: 10/8/80-by phone
FT:wcm: 10/8/80

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COI UMBIA

Civil Action No. 80-3110

COMMUNITY NUTRITION INSTITUTE, ET AL., PLAINTIFFS,

v.

ARTHUR HULL HAYES, JR., COMMISSIONER,
FOOD AND DRUG ADMINISTRATION, DEFENDANT.

DEFENDANT'S RESPONSE TO PLAINTIFFS' STATEMENT OF MATERIAL FACTS AS TO WHICH THERE IS NO GENUINE ISSUE

Pursuant to Rule 1-9(h) of the Rules of this Court, defendant submits its statement of genuine issues and its response to plaintiffs' statement of material facts as to which there is no genuine issue:

1. Paragraph 1 is admitted.

2. Paragraph 2 is admitted except to the extent that plaintiffs suggest that all aflatoxins are liver carcinogens in all test animals. The Federal Register Notice plaintiffs cite states that certain of the aflatoxins are liver carcinogens in some species of test animals.

3. Paragraph 3 is admitted except to the extent that plaintiffs suggest that the studies discussed in the Federal Register Notice plaintiffs cite do anything more than indicate a general correlation between the incidence of primary liver cancer in humans and exposure to aflatoxins in several population groups in Southeast Asia and Africa, where (a) the level of aflatoxin contamination of corn and peanuts averaged around 100 parts per billion (ppb) in 95 and 80 percent, respectively, of the samples, (b) 20 percent

of the food staples contained an average of 300 ppb aflatoxin, or (c) there was a high incidence (7 percent) of low levels (3-4 ppb) of aflatoxin in family meals.

4-6. Paragraphs 4-6 are admitted.

7. Paragraph 7 is admitted except to deny that the exemption to which plaintiffs refer was an exemption from 21 C.F.R. § 110.99(d). Section 110.99(d) has nothing to do with corn for animal feed, action levels, or blending corn—whether for consumption by man or any other animal—containing aflatoxins in excess of FDA's 20 ppb action level with corn containing less than 20 ppb aflatoxins. Statement of Taylor M. Quinn, ¶ 12.

8. Paragraph 8 is admitted except to deny that the exemption to which plaintiffs refer was granted in 1978. The exemption was granted in 1980. 48 Fed. Reg. 7,447 (January 23, 1981).

9-10. Paragraphs 9 and 10 are admitted.

11. Paragraph 11 is admitted except to deny that plaintiff Community Nutrition Institute opposed, by letter to FDA dated October 6, 1980, any of the FDA actions challeged in this case except the exemptions granted in 1980. Indeed, none of the plaintiffs has ever brought to FDA's attention, except in the context of this case, any of the actions plaintiffs challenge here other than those exemptions. Statement of Linda M. Quinones, ¶ 's 4-9.

12-14. Paragraphs 12-14 are admitted.

Respectfully submitted,

/s/
STANLEY R. HARRIS
United States Attorney

/s/
ROYCE C. LAMBERTH
Assistant United States Attorney

/s/
PATRICIA J. KENNEY
Assistant United States Attorney

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/s/
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/s/
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Consumer Affairs Section
Antitrust Division
Department of Justice

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 80-3110

COMMUNITY NUTRITION INSTITUTE ET AL., PLAINTIFFS,

v.

ARTHUR HULL HAYES, JR. COMMISSIONER, FOOD AND DRUG ADMINSTRATION, DEFENDANT.

DEFENDANT'S STATEMENT OF MATERIAL FACTS AS TO WHICH THERE IS NO GENUINE DISPUTE

Pursuant to Rule 1-9(h) of the Rules of this Court, defendant submits the following statement of material facts as to which there is no genuine dispute.

1. Plaintiff Community Nutrition Institute ("CNI") is a non-profit organization. CNI long has been active in opposing the sale of foods containing unsafe food additives and ingredients. (Complaint ¶ 4.)

2. Plaintiff Public Citizen is a non-profit organization. Its Health Research Group ("HRG") is engaged in research and advocacy to promote safe and effective food and drugs. (Complaint, ¶ 5.)

3. Plaintiff Linda S. Bardot is an employee of CNI. She and her family are consumers who eat poultry, beef, and pork, all of which may be derived from animals raised in part on corn. (Complaint, ¶ 6.)

4. Plaintiff Laura A. Rogers is a consumer who eats poultry, beef, and pork, all of which may be derived from animals raised in part on corn. (Complaint, ¶ 7.)

5. Named defendant Jere G. Goyan was the Commissioner of Food and Drugs at the time of the acts alleged in the Complaint. As Commissioner, and pursuant to 21 C.F.R. § 5.1, he acted as the designate of the Secretary of

Health and Human Services in enforcing provisions of the Federal Food, Drug and Cosmetic Act (the "Act"), 21 U.S.C. § 301 *et seq.* He was succeeded in office by Arthur Hull Hayes, Jr. on April 13, 1981.

6. The aflatoxins are a group of chemically related substances produced as natural by-products of the growth of certain common molds. The toxicity of aflatoxins, the manner in which they can contaminate foods, and the unavoidability of the contamination are described in "Aflatoxin-Contaminated Corn; Limited Exemptions from Prohibition of Interstate Shipment and Blending: Assessments of Safety and Impact in the National Food Supply," Food and Drug Administration, December (1980), pp. 1, 2, 7, 8 (the "Safety Assessment"), attached as Exhibit 7 to the Statement of Taylor M. Quinn, and incorporated by reference.

7. In the United States, the levels of aflatoxin in corn vary from region to region and within regions, from year to year. Statement of Leonard Stoloff, ¶ 's 5-11.

8. Residues of aflatoxin may appear in the edible tissues, eggs, and milk of animals fed aflatoxin-contaminated feeds, including corn. There is, however, no known method for removing aflatoxin residues from meat, eggs, milk, or dairy products after contamination has occurred. Safety Assessment, pp. 7-8.

9. FDA enforces 21 U.S.C. § 342(a)(1) against aflatoxin in corn and other susceptible commodities by means of an internal regulatory standard, called an "action level," which represents the agency's prosecutorial judgment as to the level of contamination at which the FDA is prepared to recommend to the United States Department of Justice regulatory action under the Act—seizure (21 U.S.C. § 334), injunction (21 U.S.C. § 332), or prosecution (21 U.S.C. §§ 331, 333). Since 1969, the agency's action level for aflatoxin in human food and animal feed has been 20 parts per billion (ppb). Statement of Taylor M. Quinn, ¶ 4.

10. The basis for the action level is described in the Quinn Statement, ¶'s 5,6,7, and incorporated by reference. An "action level" is not the same as a "defect action level." Defect action levels apply solely to natural or unavoidable non-hazardous defects in food—"esthetic" adulterants such as microscopic amounts of tomato mold and rot in processed tomato products—and have nothing to do with action levels, which apply solely to poisonous or deleterious substances in food. *Id.*, ¶ 12.

11. Corn containing up to 100 ppb aflatoxin does not present a reasonable possiblility of injury either to the health of mature, non-lactating livestock (beef cattle or swine) or mature poultry or to the health of humans who consume meat or eggs derived from these animals. Stoloff Statement, ¶ 4; Quinn Statement, ¶'s 6-7; Safety Assessment, p. 5. Indeed, meat from beef cattle, poultry, swine, and eggs from laying hens fed corn containing up to 100 ppb aflatoxin contain less than 0.1 ppb aflatoxin, the lowest level that can be consistently identified and measured in tissues by available analytical methods. Safety Assessment, pp. 3-6.

12. In 1978, under 21 C.F.R. § 509.8, FDA established a limited exemption to its prohibition against blending corn containing aflatoxin above its 20 ppb action level with less contaminated corn to achieve a level below 20 ppb, and then shipping the corn in interstate commerce. Notice of the exemption was published in the Federal Register of April 4, 1978 (43 Fed. Reg. 14,122), and the information supporting FDA's determinations was referred to in the notice and placed in the administrative file. The exemption applied only to corn harvested in 1977 in the southeast United States and required, among other things, that FDA approve a plan for blending before blending operations began and before the corn had been shipped in interstate commerce. *Id.* at 14,123.

The exemption established in the 1978 notice expired on January 1, 1979. *Id.* No firm or individual ever sought to take advantage of the exemption by requesting that FDA approve a plan for blending. Quinn Statement, ¶ 9(a). No comments on the 1978 notice were received from any of the plaintiffs. Statement of Linda M. Quinones, ¶ 2.

13. In September and October 1980, the States of North Carolina and South Carolina and the Commonwealth of Virginia requested limited exemptions from FDA's prohibition of interstate shipment and blending of corn containing aflatoxin above its 20 ppb action level.

In November 1980, under 21 C.F.R. § 509.8, FDA granted the states' requests for exemptions. The exemptions, which expired on January 1, 1982, were announced by a notice published in the Federal Register of January 23, 1981. 46 Fed. Reg. 7,447-7,449. The information on the basis of which FDA granted the exemptions includes the Safety Assessment and 18 documents, primarily published studies about aflatoxin, referred to therein. Quinn Statement, ¶ 9(b).

The state exemptions applied only to the 1980 corn crop harvested in North Carolina, South Carolina, and Virginia and provided that FDA would not recommend regulatory action against such corn and which contained between 20 ppb and 100 ppb aflatoxin or which was blended to achieve a level of no more than 100 ppb aflatoxin if, among other things, the corn was used only for feeding mature, nonlactating livestock and mature poultry. 46 Fed. Reg. at 7,448. The notice stated that in all other cases, FDA's prohibition of interstate shipment and blending of corn containing aflatoxin in excess of the agency's 20 ppb level "will be applied." *Id.* at 7,449; Quinn Statement, 9(b).

The state exemptions did not grant permission to ship a single lot of aflatoxin contamined corn; rather, they specified a procedure under which lots of aflatoxin-contaminated corn could be shipped in interstate com-

merce once specific terms and conditions were met. Thus, a decision by FDA not to recommend regulatory action against corn subject to the exemptions was contingent upon state and industry compliance with detailed control plans designed to ensure that (1) corn containing between 20 ppb and 100 ppb aflatoxin was not diverted for uses other than as feed for the above animals and (2) blending of corn achieved a level of no more than 100 ppb aflatoxin.

Although the exemptions required that any firm or individual wishing to take advantage of them apply to the states involved for permission to ship or blend and then ship in interstate commerce corn subject to the exemptions, the exemptions also required that FDA be notified before any shipment was made and when the shipment was received. FDA, therefore, closely monitored the exemptions, and enforced compliance with them. *Id.*, ¶ 's 9(b), 11.

14. By letter to defendant dated October 6, 1980, CNI urged FDA to deny North Carolina's and South Carolina's requests for exemptions, as well as any similar request the agency might receive. By letter to CNI dated November 28, 1980, FDA responded to each of CNI's objections, and rejected the Institute's request that the agency not grant an exemption either from the 20 ppb action level or the policy prohibiting blending. *Id.*, ¶ 10.

15. The state exemptions expired on January 1, 1982. 46 Fed. Reg. 7,447. Two shipments containing a total of seven railcars of aflatoxin-contaminated corn were made under the exemptions, one on April 15, 1981, and the other on April 21, 1981. Quinn Statement, ¶ 9(b).

16. No petition pursuant to 21 C.F.R. § 10.25, 21 C.F.R. § 109.5, or 21 C.F.R. § 509.5 for the establishment of a formal tolerance for aflatoxin in corn has been received from any of the plaintiffs. Quinones Statement, ¶ 4.

17. No comments were received from CNI, Linda S. Bardot or Laura A. Rodgers concerning FDA's Notice of proposed rulemaking for "Poisonous or Deleterious Substances in Food," 39 Fed. Reg. 42,743 (December 6, 1974) (Docket No. 77N-0166). Quinones Statement, ¶ 9.

18. FDA received a letter dated February 24, 1975, from Public Citizen, through HRG, commenting on FDA's "Proposed Tolerance; Aflatoxin in Shelled Peanuts and Peanut Products Used as Human Food," Federal Register Notice of December 6, 1974 (39 Fed. Reg. 42,748) (Docket No. 78N-0048). Quinones Statement, ¶ 10.

Respectfully submitted,

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 80-3110

COMMUNITY NUTRITION INSTITUTE ET AL., PLAINTIFFS,

v.

ARTHUR HULL HAYES, JR. COMMISSIONER, FOOD AND DRUG ADMINSTRATION, DEFENDANT.

STATEMENT OF TAYLOR M. QUINN

1. I, Taylor M. Quinn, am Associate Director for Compliance, Bureau of Foods, United States Food and Drug Administration ("FDA"). In this capacity I am responsible for FDA's enforcement of the provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, pertaining to food. I have been involved in the enforcement of the Act for about 30 years, including 11 years as an Inspector, 9 years as a Consumer Safety Officer, 6 years as Director of the Division of Regulatory Guidance, Bureau of Foods, and nearly 4 years in my present position.

2. My duties require that I be, and I am, generally familiar with problems related to aflatoxin-contamination of food, including how the contamination occurs, what can and cannot be done to prevent the contamination, and the nature of the risks to health presented by the contamination. My knowledge in this area is obtained through a variety of methods, including reading of published and unpublished reports, discussions with plant pathologists, toxicologists, public health officials, and agency personnel, and meetings with members of the food industry.

3. During the course of my official duties, I participated in the formulation of FDA's regulatory policy with respect to aflatoxin-contaminated foods, including corn, and FDA's regulations on poisonous and deleterious substances in human food and animal feed, 21 C.F.R. §§ 109 and 509.

4. Under the FD&C Act, a food is deemed to be adulterated if, among other things, it bears or contains an added poisonous or added deleterious substance which may render the food injurious to health. 21 U.S.C. § 342(a)(1). Thus, a food is adulterated within the meaning of section 342(a)(1) if it presents a reasonable possibility of injury to humans or animals. FDA guides enforcement under 21 U.S.C. § 342(a)(1) against aflatoxin in corn and other susceptible commodities by means of internal regulatory standard, called an "action level," which represents the agency's prosecutorial judgment as to the level of contamination at which FDA is prepared to recommend to the United States Department of Justice regulatory action under the Act—seizure (21 U.S.C. § 334), injunction (21 U.S.C. § 332), or prosecution (21 U.S.C. §§ 331, 333). Since 1969, the agency's action level for aflatoxin in food and feed has been 20 parts per billion (ppb).

5. The action level is based on four considerations:

(a) Direct consumption by humans of agricultural commodities containing more than 20 ppb aflatoxin may be injurious to their health;

(b) Milk from dairy cattle fed corn or other commodities containing more than 20 ppb aflatoxin may be injurious to the health of infants because residues of aflatoxin may appear in the milk of such cattle. Milk, of course, occupies a unique position in the diet of infants.

(c) Direct consumption by young animals of feed containing more than 20 ppb aflatoxin may be injurious to their health; and

(d) Although consumption by most food producing animals would raise no public health concern, FDA does not have the enforcement resources to ensure that agricultural commodities containing more than 20 ppb aflatoxin are not used as food for humans, dairy cattle, or young animals.

6. FDA has not determined that animal feed, including corn, containing more than 20 ppb aflatoxin, may be injurious to all species of food producing animals or to humans who consume edible products from such animals. Indeed, to FDA's knowledge there is no qualified expert who will testify that corn containing between 20 ppb and 100 ppb aflatoxin presents a reasonable possibility of injury to mature, nonlactating livestock (beef cattle or swine) or mature poultry, or to humans who consume meat or eggs from those animals. Nonetheless, to ensure that no corn containing more than 20 ppb aflatoxin is consumed by humans, dairy cattle, or young animals, FDA's action level calls for regulatory action against all corn containing more than 20 ppb aflatoxin.

7. It has not been proved that the meat or eggs from mature, nonlactating livestock or mature poultry fed corn containing between 20 ppb and 100 ppb aflatoxin are safe—i.e., without any risk—for human consumption. As discussed in paragraph 6, however, FDA cannot show that such corn presents a reasonable possibility of injury either to those animals or to humans who consume edible products from then, and therefore lacks the evidence to support a charge of food adulteration under 21 U.S.C. § 342(a)(1). Thus, agency recommendations for regulatory action against corn containing between 20 ppb and 100 ppb aflatoxin often are made because at the time of the incipient seizure or injunction, FDA does not know the destination of the corn and will not risk the possibility that the corn ultimately will be consumed by humans, dairy cattle, or young animals instead of mature beef cattle, poultry, or swine.

8. Corn containing above 20 ppb aflatoxin and which has moved in interstate commerce, though above the agency's action level, is not automatically the subject of a recommendation for enforcement litigation. FDA regulations authorize the FDA to exempt from a recommendation for regulatory action any food containing a poisonous and deleterious substance if the agency determines that (1) based on all available evidence, the food is "safe" for consumption—i.e., involves no "significant health hazard," 39 Fed. Reg. 42743, 42746 (December 6, 1974)—and (2) destruction or diversion of the food would result in a substantial adverse impact on the national food supply. 21 C.F.R. §§ 109.8 (human food), 509.8 (animal feed). The regulations require publication in the Federal Register of FDA's determinations, an invitation to comment on them, and inclusion in the administrative file of the information supporting them.

9. FDA has granted exemptions under 21 CFR 509.8 on two occasions.

(a) In 1978, FDA established a limited exemption to its prohibition against blending corn containing aflatoxin above its 20 ppb action level with less contaminated corn to achieve a level below 20 ppb and then shipping the corn in interstate commerce. Notice of the exemption was published in the Federal Register of April 4, 1978 (43 Fed. Reg. 14122), and the information supporting FDA's determinations was referred to in the notice and placed in the administrative file. The exemption applied only to corn harvested in 1977 in the southeast United States and required, among other things, that FDA approve a plan for blending before blending operations began and before the corn had been shipped in interstate commerce. *Id.* at 14123.

The exemption established in the 1978 notice expired on January 1, 1979. *Id.* No firm or individual ever sought to take advantage of the exemption by requesting that FDA approve a plan for blending.

(b) In September and October 1980, the States of North Carolina and South Carolina and the Commonwealth of Virginia requested limited exemptions from FDA's prohibition of interstate shipment and blending of corn containing aflatoxin above its 20 ppb action level. These requests are attached hereto as Exhibits 1-3.

In November 1980, pursuant to and in accordance with 21 C.F.R. § 509.8, FDA granted the States' requests for exemptions. FDA's correspondence with the States is attached hereto as Exhibits 4-6. The exemptions, which expired on January 1, 1982, were announced by a notice published in the Federal Register of January 23, 1981. 46 Fed. Reg. 7447-7449. Only two shipments totalling seven railroad cars of aflatoxin contaminated corn were made under the exemptions, one on April 15, 1981, and the other on April 21, 1981, from South Carolina to Florida. The information on the basis of which FDA granted the exemptions includes "Aflatoxin-Contaminated Corn; Limited Exemptions from Prohibition and Interstate Shipment and Blending: Assessments of Safety and Impact on the National Food Supply," Food and Drug Administration, December 1980, and eighteen documents, primarily published studies about aflatoxin, referred to therein. The Assessment is attached hereto as Exhibit 7; the supporting documents are attched as Exhibits 1-18 to the Statement of Linda M. Quinones, Director, Dockets Management Branch, United States Food and Drug Administration filed with the Court.

The state exemptions applied only to the 1980 corn crop harvested in North Carolina, South Carolina, and Virginia and provide that FDA would not recommend regulatory action against such corn and which contained between 20 ppb and 100 ppb aflatoxin or which had been blended to achieve a level of no more than 100 ppb aflatoxin if, among other things, the corn was used only for feeding mature, nonlactating livestock and mature poultry.

46 Fed. Reg. at 7448. The notice stated that in all other cases, FDA's prohibition of interstate shipment and blending of corn containing aflatoxin in excess of the agency's 20 ppb action level "will be applied." *Id.* at 7449. Thus, the action level remains in effect and will be applied whenever (as is always true) the facts and circumstances of a particular shipment warrant a recommendation for regulatory action. Those facts and circumstances include the quantity of contaminated food or feed, the level of contamination, and the ultimate consumer (humans or animals, species, age.).

The state exemptions did not grant permission to ship a single lot of aflatoxin-contaminated corn; rather, they specified a procedure under which certain lots of aflatoxin-contaminated corn could be shipped in interstate commerce once specific terms and conditions were met. Thus, a decision by FDA to not recommend regulatory action against corn subject to the exemptions was contingent upon state and industry compliance with detailed control plans designed to ensure that (1) corn containing between 20 ppb and 100 ppb aflatoxin is not diverted for uses other than as feed for the above animals and (2) blending of corn achieves a level of no more than 100 ppb aflatoxin. The control plans were in large part developed by each of the three states, and were included as part of their exemption requests submitted to FDA.

Although the exemptions required that any firm or individual wishing to take advantage of them to apply to the states involved for permission to ship or blend and then ship in interstate commerce corn subject to the exemptions, the exemptions also required that FDA be notified before any shipment was made and when any shipment was received. FDA, therefore, closely monitored the exemptions.

The States of South Carolina and Georgia have made requests to FDA that exemptions be granted for corn harvested in their states in 1981. FDA has made no formal reply.

10. By letter to defendant dated October 6, 1980 plaintiff Community Nutrition Institute (CNI) urged FDA to deny North Carolina's and South Carolina's requests for exemptions, as well as any similar request the agency might receive. A copy of CNI's letter is attached hereto as Exhibit 8. A copy of FDA's response is attached hereto as Exhibit 9.

11. FDA will enforce compliance with the exemptions by revoking its commitment to not recommend regulatory action if FDA, through its monitoring or any other activities, finds that a state is not complying with the terms and conditions of the exemptions.

12. Plaintiffs allege that 21 C.F.R. § 110.99(d) prohibits blending food containing a poisonous and deleterious substance, for example, aflatoxin-contaminated corn, with another lot of food (Complaint, ¶ 17). Plaintiffs are wrong. Section 110.99(d) applies solely to unavoidable, non-hazardous defects in human food, for example, microscopic amounts of tomato mold and rot in processed tomato products. The phrase "defect action level" in 21 C.F.R. § 110.99(d) pertains solely to "esthetic" or "cosmetic" adulterants in food. "Defect action levels" have nothing to do with poisonous or deleterious substances in food, for example, aflatoxin in corn, and should not be confused with "action levels," described in paragraph 4.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing statement is true and correct.

Excuted on April ____, 1982.

TAYLOR M. QUINN
Associate Director for Compliance
Bureau of Foods
United States Food and Drug
Administration
Washington, D.C.

EXHIBIT 4

TELEGRAPHIC MESSAGE **CA 80-3110**

To: James A. Graham, Commissioner, Department of Agriculture, State of North Carolina

From: Associate Commissioner for Regulatory Affairs, Food and Drug Administration

This is to advise you that we have completed our review of the "North Carolina plan for control of interstate shipments of corn bearing or containing not more than 100 parts per billion aflatoxin," as revised in accordance with comments contained in our NRSTEN TWX of October 9, 1980. This revised plan adequately addresses previous comments and may be implemented immediately.

If any problems are encountered in implementing the plan Mr. Taylor M. Quinn (202-245-1243) or our Atlanta regional office should be advised immediately. Similarly, if evidence comes to our attention that the plan is not working in any particular way we will advise your office immediately to resolve the problems.

EXHIBIT 5

TELEGRAPHIC MESSAGE **CA 80-3110**

To: G. Bryan Patrick, Jr., Commissioner, Department of Agriculture, State of South Carolina

From: Associate Commissioner for Regulatory Affairs, Food and Drug Administration

This is to advise you that we have completed our review of the "South Carolina plan for control of interstate shipments of corn bearing or containing not more than 100 parts per billion aflatoxin," as revised in accordance with comments contained in our NRSTEN TWX of October 9, 1980. This revised plan adequately addresses previous comments and may be implemented immediately.

If any problems are encountered in implementing the plan Mr. Taylor M. Quinn (202-245-1243) or our Atlanta regional office should be advised immediately. Similarly, if evidence comes to our attention that the plan is not working in any particular way we will advise your office immediately to resolve the problems.

EXHIBIT 6

TELEGRAPHIC MESSAGE **CA 80-3110**

To: S. Mason Carbaugh, Commissioner, Virginia Department of Agriculture and Consumer Services

From: Associate Commissioner for Regulatory Affairs, Food and Drug Administration

This is to advise you that we have completed our review of the "Virginia plan for control of interstate shipments of corn bearing or containing not more than 100 parts per billion aflatoxin," as revised in accordance with comments contained in our NRSTEN TWX of October 9, 1980. This revised plan adequately addresses previous comments and may be implemented immediately.

If any problems are encountered in implementing the plan Mr. Taylor M. Quinn (202-245-1243) or our Philadelphia regional office should be advised immediately. Similarly, if evidence comes to our attention that the plan is not working in any particular way we will advise your office immediately to resolve the problems.

EXHIBIT 7
CA 80-3110
AFLATOXIN-CONTAMINATED CORN
LIMITED EXEMPTIONS FROM PROHIBITION
OF INTERSTATE SHIPMENT AND BLENDING

ASSESSMENTS OF SAFETY

AND

IMPACT ON THE NATIONAL FOOD SUPPLY

FOOD AND DRUG ADMINISTRATION
DECEMBER 1980

BACKGROUND

The Food and Drug Administration (FDA) has an established action level of 20 parts per billion (ppb) for aflatoxin contamination of corn for human or animal consumption (FDA Administrative Guidelines Manual, 7420.01 (5/16/79)).

FDA's regulations on Unavoidable Contaminants in Animal Food-Packaging Material, 21 CFR 509.8, provides for exemptions from established action levels based on all available evidence that the food is safe for consumption (i.e., no significant health hazard is involved) and that destruction or diversion of the food involved would result in a substantial adverse impact on the national food supply.

In order to determine whether to grant limited exemptions to its existing policy prohibiting the interstate shipment and blending of corn containing aflatoxin above the action level with less contaminated corn, FDA has considered the safety of such action and its impact on the national food supply. These exemptions provide for interstate shipment of corn containing aflatoxins up to a level of 100 ppb and the blending of aflatoxin contaminated corn to achieve aflatoxin levels of 100 ppb or

less. Under the exemptions, such corn is restricted to use as feed or feed ingredients for mature nonlactating livestock and mature poultry. The exemptions were requested by the states of North Carolina and South Carolina and the Commonwealth of Virginia.

Aflatoxins are a group of highly toxic chemicals produced by molds that can sometimes contaminate susceptible foods such as peanuts and corn. One of the aflatoxins, known as B_1, is a potent liver carcinogen in some species of experimental animals. Information bearing on the assessment of possible hazard to humans from aflatoxin ingestion is presented (reference 1).

FDA imposed regulatory guidelines to limit the aflatoxin content of peanuts, corn, their manufactured products, and other susceptible commodities. A limit of 30 ppb total aflatoxins (four toxins, called B_1, B_2, G_1 and G_2) based on analytical capability was set in 1965. In 1969, based on improvements in analytical capability, this guideline was reduced to 20 ppb, where it stands today.

SUMMARY OF EVIDENCE OF SAFETY

Aflatoxin contamination of feed corn is of concern because it can affect animal health, and because such animals provide edible tissues (meat, milk, and eggs) for human consumption. When feed containing aflatoxins is ingested by dairy cattle, beef cattle, poultry, or swine, the largest portion of the aflatoxins is eliminated in excreta, but residues of aflatoxins may be found in the edible tissues of those animals under certain circumstances.

Both unmetabolized aflatoxin B_1 and the chemically related but less potent carcinogen, aflatoxin M_1 (a compound produced from B_1 by normal biological processes of the ingesting animals, i.e., M_1 is a metabolite of B_1), can sometimes be detected as residues in edible tissues. Almost all studies related to aflatoxins fed to livestock are based on examination of edible tissues for B_1 and M_1.

Other aflatoxins, e.g., B_2, G_1, and G_2, usually occur at levels substantially lower than B_1; consequently, they have been found in edible tissue only after feeding of aflatoxins at levels so high that animal health is affected. The quantitative relationships between feed levels of aflatoxins and edible tissue levels of B_1 and M_1 is considered below.

- An analysis has been made of currently available information regarding aflatoxin. It has been determined that 0.1 ppb aflatoxin is the lowest level that can be consisently identified and measured in tissues by available analytical methods (references 2, 3, and 4).

Information on the quantitative relationships between feed levels of aflatoxins and levels of aflatoxin residues occurring in edible tissues has been assembled and assessed (references 5, 6, and 7). The studies which produced this information varied considerably in the dosing schedule of the animals, the breed of animals, the mode of administration of the aflatoxins, the levels of aflatoxins administered, the experimental period, and the source of aflatoxin used (e.g., purified B_1 vs. mold-contaminated feed).

A tabular review (reference 9) of information pertinent to this assessment from published reports through 1977 is presented. This includes information on the specific tissues in which aflatoxin residues occur. For each major food-producing animal, the single tissue and type of aflatoxin which together provide the lowest feed to tissue ratio were selected. Where both B_1 and M_1 occurred as residues, B_1 was chosen as the aflatoxin of interest because of its predominance and its more potent carcinogenic properties compared to M_1. By the above criteria the aflatoxin and edible tissues that provide the most sensitive indicator of aflatoxin contamination are: aflatoxin B_1 in the livers of beef cattle, swine and broilers, aflatoxin B_1 in eggs, and aflatoxin M_1 in the milk of dairy cattle.

Based on the foregoing information, the most likely ratios of the level of aflatoxin B_1 in feed to the level of aflatoxin B_1 or M_1 in various edible tissues have been estimated. These are presented in Table I.

Table I

Animal	Edible Tissue	Aflatoxin in Tissue	Estimated Aflatoxin Feed/Tissue Ratio
Beef cattle	Liver	B_1	14,000
Dairy cattle	Milk	M_1	300
Swine	Liver	B_1	800
Layers	Eggs	B_1	2,200
Broilers	Liver	B_1	1,200

The aflatoxin B_1 levels in feed which might result in the minimum measurable residue of aflatoxin in tissue (0.1 ppb) are about 1/10th of the values in the last column of Table I, e.g. 1400 ppb aflatoxin in the feed of beef cattle would result in a estimated 0.1 ppb aflatoxin in the edible tissue (i.e. liver) of the cattle.

On the basis of the above estimates, FDA concluded that an exemption could be made to the existing action level of 20 ppb aflatoxins in corn intended for use as an ingredient in the feed rations of certain food-producing animals. Specifically, the agency concluded that corn containing up to 100 ppb aflatoxins could be fed to mature cattle (except lactating dairy cattle), swine and poultry without posing a significant health hazard or even a significant increase in risk to consumers of food from these animals. This conclusion is based on the following considerations. The existing level of 20 ppb, which is applicable to individual feed ingredients, as well as complete feed rations, ensures that aflatoxins will not occur at levels

higher than 0.1 ppb in edible tissues of animals. Levels of 0.1 ppb or less aflatoxin in food derived from animals represents an insignificant fraction of the total human dietary exposure to aflatoxins.

According to Table I, and since corn does not usually comprise an animal's total ration, aflatoxin B_1 levels up to 100 ppb in corn fed to mature nonlactating livestock and mature poultry also should not cause a level of aflatoxin in edible tissues above 0.1 ppb.

The 800:1 feed:tissue ratio for swine in Table I does indicate that residues might be detected in swine liver when aflatoxin levels exceed 80 ppb in the animal's total ration. However, because corn is usually fed with other ingredients, the aflatoxin levels in the total swine ration will be lower than in the corn alone. Accordingly, aflatoxin residues in the liver from the total ration are not expected to exceed the 0.1 ppb level of detection. A practical test of experimental determinations regarding aflatoxin transfer from feed to tissue residues was conducted by the U.S. Department of Agriculture's Food Safety and Quality Service (FSOS) for a year starting October 1977, when again much of the Southeastern corn crop was contaminated with aflatoxins at levels frequently exceeding 100 ppb. See "Notice; Aflatoxin Contaminated Corn, Limited Exemption from Blending Prohibition," 43 *Federal Register*, 14122, 14123 (April 4, 1978). Random samples of hog, cattle, and poultry livers, as well as liquid eggs, in the Southeast were analyzed for aflatoxins by a method capable of detecting 0.05 ppb. No aflatoxin was detected in any sample (reference 10). An FDA survey of shell eggs on the Southeast retail market in November 1977 also failed to detect aflatoxin (reference 11). Therefore, allowing corn containing up to 100 ppb total aflatoxins to be used for the animals listed above would not pose a significant health hazard or even significantly increase the risk to the public health from dietary exposures to aflatoxin.

The 20 ppb action level for dairy animal feed and feed ingredients also prevents detectable residues from occurring in milk. However, as can be seen in Table I, aflatoxin contamination levels somewhat above the 20 ppb action level can cause detectable residues of M_1 in milk. Because of the unique position of milk in the infant diet and because the very young might be more susceptible to the effects of aflatoxins (reference 12), corn containing aflatoxins at levels above 20 ppb is not permitted in the feed of lactating dairy animals under the exemptions.

The safety of the contaminated feed for ingestion by animals must also be considered. Available information on the affects of aflatoxins on the health of various food-producing animals has been reviewed (references 7, 8, 13, and 14). Although levels of dietary aflatoxins which produce no adverse affects in livestock cannot be sharply defined from the available information, it is possible to make judgments about the probability of adverse effects.

The 100 ppb level for total aflatoxins is below any aflatoxin B_1 level that has caused adverse effects to mature livestock and poultry. However, the susceptibility of the very young to aflatoxicosis applies not just to humans, but to all animals. Therefore, no exemption for starter ration ingredients (i.e., feed for young animals) is being made.

AFLATOXIN PREVENTION AND CONTROL

Aflatoxin contamination of meat, milk, and eggs can be controlled by limiting the level of aflatoxin contamination of feed. There is no known method for removing aflatoxin residues from meat, eggs, or milk, or from products derived from milk, after contamination has occurred. Aflatoxin contamination of feeds can occur whenever conditions permit the growth of aflatoxin-producing fungi, although there is no evidence that the growth of aflatoxin-producing fungi always results in toxin production (reference 15). Aflatoxins may be found even when mold

growth is not visually obvious or has been obscured by blending or processing. Therefore, the presence and concentrations of aflatoxins must be determined by chemical analysis for the aflatoxins themselves.

Although improper storage or inadequate drying of corn can cause growth of aflatoxin-producing molds after harvest, investigation into the causes of aflatoxin contamination has shown that contamination of corn frequently occurs prior to or during harvest. Insect damage, environmental stresses (e.g., drought and hail), and plant variety have also been shown to increase susceptibility of corn to mold growth (reference 16).

Until the environmental and agronomic factors relating to aflatoxin contamination are better understood and agricultural practices are adjusted to better control mold growth in the field, there will continue to be some level of aflatoxin contamination in corn and other susceptible commodities.

SUMMARY OF IMPACT ON NATIONAL FOOD SUPPLY

Aflatoxin contamination of the 1980 corn crop has reached disastrous proportions in the states of North and South Carolina and is significant in the Commonwealth of Virginia. Data included with the exemption requests from the States indicate that 63 percent of North Carolina's, 73 percent of South Carolina's, and up to 23 percent of Virginia's 1980 corn crop exceeds the 20 ppb action level. Data from other southeastern states indicate there may be a significant problem with aflatoxin contamination of 1980 harvested corn for the entire region (references 15 and 16) which may result in requests from other States for similar exemptions.

Due to the severe aflatoxin contamination of the 1980 corn crop in these states, much of their corn harvest could not be legally marketed in interstate commerce. By allowing these three states the use of blended or nonblended corn with aflatoxin levels not exceeding 100 ppb, it is anticipated that the available corn will be increased by approximately 101.4 million bushels, valued at 319.5 million dollars at current market prices.

CONCLUSIONS

Safety—Based upon all available evidence, the limited exemptions to the existing aflatoxin action level for feed corn will not result in an increased risk to the health of animals fed such corn, or to humans consuming edible tissues derived from those animals; and therefore, will not result in a significant health hazard for humans or other animals. It may also relieve local pressures to use contaminated corn for milling into food or dairy rations. These exemptions shall be applicable only to corn from the 1980 crop harvested in North Carolina, South Carolina and Virginia for consumption by mature, non-lactating livestock and mature poultry. Safety considerations dictate that corn moving in interstate commerce contain no more than 100 ppb.

National Food Supply—The destruction or diversion of corn required by the existing action level would result in a substantial adverse impact on the national food supply. Under the limited exemptions, the marketable feed corn from the 1980 crop in North and South Carolina and Virginia will be substantially increased.

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17. Memo—"Florida State Evaluation of Aflatoxin Problem—1980 Corn Crop" September 30, 1980.

18. Memo—"1980 Corn Crop." September 12, 1980.

EXHIBIT 9

CA 80-31 EX 9

DEPARTMENT OF HEALTH, EDUCATION
AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

NOV 28, 1980

Ms. Ellen Haas
Director
Ms. Thomas B. Smith
Research Director
Consumer Division
Community Nutrition Institute
1146 19th Street, N.W.
Washington, D.C. 20036

Dear Ms. Haas and Mr. Smith:

This responds to your letter dated October 6, 1980, expressing concern about proposals submitted to FDA by the States of North and South Carolina. These proposals request FDA to temporarily exempt corn produced in certain regions of the U.S. from our current action level for aflatoxin of 20 ppb when such corn is shipped in interstate commerce and to permit blending of corn to achieve levels of no more than 100 ppb aflatoxin provided certain conditions are met. These proposals, an additional one from Virginia, and the plans for controlling interstate shipments of corn containing not more than 100 ppb aflatoxin have now been approved. I understand that you have been sent copies of our responses to North and South Carolina which detail the stringent conditions under which the corn shipments will be allowed. We will shortly be publishing in

the *Federal Register* a notice stating the limited exemptions from the prohibition of interstate shipment and blending of corn containing more than 20 ppb aflatoxin.

I want to assure you that this Agency is committed to the protection of the public health. In reaching a decision on this matter, we have considered whether the corn is safe for consumption and whether destruction or diversion of the corn would have a substantial impact on the national food supply. (See the enclosed copy of 21 CFR 509.8.) Our decision has taken into account all available scientific evidence. The protection of the public health was—and remains—our main concern.

Your letter quotes several articles, studies, and reports which you believe support your present concern over the feeding of corn containing up to 100 ppb of aflatoxin to mature, non-lactating livestock and poultry. I would like to address some of the issues you have raised, in the context of the factors we considered in arriving at our decision.

Our overall policy on aflatoxin is still to reduce human exposure to as low a level as is technologically feasible; our decision concerning the 1980 corn harvest is consistent with this policy. Aflatoxins may occur naturally in certain products such as corn, most often as a result of adverse weather conditions. They can also occur as a result of improper harvesting and storage procedures, which can be controlled by man; efforts are continually being made to improve these procedures. Investigators are exploring safe methods of removing aflatoxin from these products. One of the most effective means founds thus far is the consumption of aflatoxin-contaminated feed by animals that metabolize aflatoxin very rapidly.

In your letter, you cite an article by Rodricks and Stoloff which delineated various feed/edible tissue ratios for aflatoxin. The feed/tissue ratios listed were instrumental in determining the best procedure for feeding

the aflatoxin-contaminated feed. As a practical matter, exposure to the maximum allowable level during the full course of feeding is not likely. *Controlled* feeding of corn containing no more than 100 ppb aflatoxin to mature non-lactating livestock and poultry is an effective way of removing aflatoxin from the corn and preventing the corn from adversely affecting human and animal health – while at the same time receiving the benefits of the use of the corn in maintaining an adequate food supply.

As you mentioned in your letter, aflatoxin is a potent carcinogen, with species susceptibility from levels as low as 0.1 ppb in trout. Several metabolites resulting from ingestion of aflatoxin-contaminated foods and feeds have been identified and the comparative toxicities established. Because such information is not available for man, assessment of human toxicity from aflatoxin is based on extrapolation of animal data. Epidemiological studies on the incidence of primary liver cancer in Southeast Asia and Central Africa have shown a possible association with the consumption of aflatoxin contamination in foods. Unfortunately, all potential causes of liver cancer could not be adequately identified in these studies. Data obtained from the National Center for Health Statistics on death due to primary liver cancer from all sources in the U.S. (attached) do not show an increased incidence for the area in question where aflatoxin contamination of foods and feeds is an annual problem. Such studies highlight the difficulty is assessing the actual risk posed to man from aflatoxin contamination.

Your letter expresses specific concern that if interstate movement of corn containing up to 100 ppb aflatoxin is allowed, such corn will inevitably finds its way into all commercial channels, including human food and dairy feed uses. On the contrary, we believe that a *controlled* plan for utilization of such corn provides the growers and elevators with a legitimate outlet for this corn, in lieu of

destruction, and will most probably eliminate the incentive for unscrupulous business interests and the hard-pressed growers to divert this corn to concerns that may manufacture human foods or dairy feeds. We have no way of knowing whether corn shipped under the controlled plans will be discounted, but we suspect that without the plan, price reduction of contaminated lots would be inevitable.

Your letter correctly notes that we have stated in the past that we do not have the resources necessary to *routinely* (emphasis added) control the ultimate use of all corn moving in interstate commerce and have steadfastly refused all requests to raise the action level to 100 ppb across the board. Under the plans thus far approved for North and South Carolina and Virginia, the ultimate use of the shipments of corn containing up to 100 ppb aflatoxin will be controlled by the cooperating States. The plans will specifically delineate the state agencies responsible for monitoring the shipments, require written assurance from the ultimate user before shipment that the corn will only be fed to mature non-lactating livestock or poultry, and require documentation that the shipment (previously labeled and appropriately sealed) reaches the ultimate user. We will monitor selected shipments to determine compliance with the plan, and we will document the appropriate end use of these shipments. If we determine that the plans are not working properly, the temporary exemption will immediately be rescinded.

We would like to point out that an integral part of these plans is the assurance that the corn to be shipped interstate does not exceed 100 ppb as determined before shipment is allowed. This assurance is obtained through a thorough sampling of each lot (if a lot is blended, sample size is doubled) and the shipment is rejected if 80 ppb (average of duplicate analyses) or more of aflatoxin is detected. In addition, if a firm wishes to blend lots to obtain a final aflatoxin level below 100 ppb, proposals must be sub-

mitted by each firm and approved by the States separately. These plans must delineate the method of blending, the aflatoxin levels of the two lots to be blended, sampling procedures during or after blending, and the final analyses of the blended lot.

To sum up, we believe there is ample scientific evidence which demonstrates that corn containing up to 100 ppb of aflatoxin can be safely fed to mature, non-lactating livestock and poultry. This level provides a sufficient margin of safety to ensure that there will be no harmful effects on animal health or unsafe residues in edible tissues. The approved plans allow further assurance, through a statistically designed sampling plan and rejection limit of 80 ppb, that each lot actually contains no more than 100 ppb. Additional assurance is provided by the results of approximately 1,000 samples of liver—beef, swine and poultry—and eggs collected by the Food Safety and Quality Service of USDA from October 1977 to October 1978, the period of time when the contaminated 1977 corn crop was being used. These samples were collected at a rate of 120 per month; no aflatoxin was detected in any sample. (Current methodology can detect approximately 0.1 ppb aflatoxin, depending on the product.)

We firmly believe that the controlled feeding of this corn to mature, non-lactating livestock and poultry is an effective means of reducing human exposure to aflatoxin and is an appropriate course of action in emergencies such as this. We repeat that we have not compromised the public health and, in fact, are making every effort to protect it without drastically affecting the food supply in this country.

Sincerely yours,

/s/

Jere E. Goyan
Commissioner of Food and Drugs

Enclosures

§ 509.8 Exemptions.

(a) The Commissioner may exempt from regulatory action and permit the marketing of any food that is unlawfully contaminated with a poisonous or deleterious substance if:

(1) He determines (i) based upon all available scientific evidence, that the food is safe for consumption and (ii) that destruction or diversion of the food involved would result in a substantial adverse impact on the national food supply.

(2) Such determination is published as a notice in the FEDERAL REGISTER and public comment shall be invited on the determination. The notice shall call attention to the material supporting the determination, which shall be on file with the Hearing Clerk before the notice is published.

(3) The determination identifies the level of contamination allowed by the exemption, and the food to which it applies, e.g., the specific growing area or other identifying information. The exemption shall not apply to any other food produced in any other area or at any other time. Contaminated food not subject to the exemption will remain subject to regulatory action.

(b) Any person responsible for contamination of the food involved, or shipment of any such food in interstate commerce prior to the issuance of an exemption pursuant to this section, shall remain subject to regulatory action pursuant to sections 302 (injunction proceedings) and 303 (penalties) of the act.

(c) In the case of a poisonous or deleterious substance which is a pesticide chemical, the level of contamination allowed by the exemption shall, upon the request of the Food and Drug Administration, be specified by the Environmental Protection Agency pursuant to paragraph (a)(1)(i) of this section and promulgated by the Commissioner. No exemption for a pesticide chemical shall be promulgated without the concurrence of the Environmental Protection Agency.

Mortality From Primary Liver Cancer by Region, by Race, by Locale from XCHS data tapes 1968-71, 1973-76

	White				Negro				Japanese		Chinese		Hawaiian	
	Male		Female		Male		Female		Male	Female	Male	Female	Male	Female
	Urban	Rural	Urban	Rural	Urban	Rural	Urban	Rural						
[(age 30-50 liver cancer deaths/all deaths)/10^5]														
Appalachia	7	13	10	7	15	6	7	8						
Delta	11	3	3	9	21	16	7	8						
Dist. Columbia	0		0		54		17							
Downeast	3	7	3	4										
Hawaii	0	0												
Midwest	7	6	6	8	43	15	16	20						
Mountain	10	6	4	8	17									
North Plains	4	6	10	6	16		0							
Northeast	7	8	5	9	31	25	17	17						
Northwest	10	3	3	13	140		0							
South Border	6	9	3	3	30	7	8	5						
South Plains	14	7	11											

Table – Continued

	White				Negro				Japanese		Chinese		Hawaiian	
	Male		Female		Male		Female		Male	Female	Male	Female	Male	Female
	Urban	Rural	Urban	Rural	Urban	Rural	Urban	Rural						
[(age 30-50 liver cancer deaths/all deaths)/10^5]														
Southeast	8	7	4	6	32	14	6	9						
Southwest	8	10	7	8	34	32	20	79						
All Areas	8	7	6	8	36	16	14	10	84	22	377	119	135	38
[(all liver cancer death/all deaths)/10^5]														
Appalachia	132	138	114	103	252	141	98	90						
Delta	147	100	66	69	131	105	39	47						
Dist. Columbia	120		81		364		160							
Downeast	89	79	73	45										
Hawaii	201	92	204	77										
Midwest	131	92	84	80	281	166	125	103						
Mountain	91	72	63	66										
North Plains	95	117	88	110	135		85							

Table – Continued

	White				Negro				Japanese		Chinese		Hawaiian	
	Male		Female		Male		Female		Male	Female	Male	Female	Male	Female
	Urban	Rural	Urban	Rural	Urban	Rural	Urban	Rural						
	[(all liver cancer deaths/all deaths)/10^5]													
Northeast	136	117	76	83	225	122	98	85						
Northwest	115	98	79	87	280		48							
South Border	109	99	68	51	229	106	104	78						
South Plains	194	160	150	140	284	259	154	104						
Southeast	127	106	79	82	167	84	63	46						
Southwest	136	125	77	83	198	303	104	210						
All Areas	134	110	84	85	232	118	100	64	560	333	1,682	595	581	510
	[total deaths in 1,000's]													
Appalachia	120	250	102	173	34	16	29	12						
Delta	89	159	72	108	47	64	40	51						
Dist. Columbia	12		12		24		18							
Downeast	31	67	29	53										
Hawaii	4	2	3	1										

Table – Continued

	White				Negro				Japanese		Chinese		Hawaiian	
	Male		Female		Male		Female		Male	Female	Male	Female	Male	Female
	Urban	Rural	Urban	Rural	Urban	Rural	Urban	Rural						
	[total deaths in 1,000's]													
Midwest	1,049	922	698	692	180	13	133	9						
Mountain	92		74											
North Plains	82	114	70	162	6		5							
Northeast	1,149	684	1,021	559	163	16	126	12						
Northwest	112	115	92	75	4		2							
South Border	103	167	88	127	47	30	35	21						
South Plains	289	230	230	163	50	22	39	17						
Southeast	317	453	250	325	115	125	96	96						
Southwest	544	222	464	154	46	6	35	4						
All Areas	3,991	3,521	3,404	2,590	718	294	559	222	12	9	12	5	4	3

(KY.TN,WV) Delta (AR, LA, MS) Downeast (ME,VH.VT) Midwest (IA, IL, IN, MI, MN, MO, OH, WS) (D, MT, UT, WY) North Plains (KS, NB, ND, SD) Northeast (CT, MA, NJ, NY, PA, RI) DR,WA) South Border (DE, MD, VA) South Plains (NM, OK, TX) Southeast (AL, FL, GA, NC, SC) Southwest (AR, CA, NV)

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 80-3110

COMMUNITY NUTRITION INSTITUTE, ET AL., PLAINTIFFS,

v.

ARTHUR HULL HAYES, JR., COMMISSIONER,
FOOD AND DRUG ADMINISTRATION, DEFENDANT.

STATEMENT OF LEONARD STOLOFF

1. I, Leonard Stoloff, am a Research Chemist in the Division of Chemistry and Physics, Bureau of Foods, United States Food and Drug Administration ("FDA"). My curriculum vitae and a list of my scientific publications are attached.

2. Since 1963, I have been involved in the supervision and performance of research on the analysis, properties, and occurrence of toxicants produced by fungi (mycotoxins), particularly the aflatoxins. Since 1970, I have been manager of the FDA, Bureau of Foods projects "Mycotoxins Literature," and "Control of Mycotoxins in Foods" As manager of the first project, I have been responsible for maintaining a current awareness of all ongoing and published research concerned with mycotoxins, accomplished through a well-developed information gathering network and an interacting computer system for citation storage. As manager of the second project, I have been responsible for translating the acquired information into rational programs for control of mycotoxins, particularly aflatoxin. I have, in this capacity, been responsible for the major portion of the technical input for the FDA programs for control of aflatoxins.

For a list of my contributions to the knowledge of aflatoxins and my participation in groups outside of FDA that are concerned with aflatoxins, see the attached list of special invitations and of publications.

3. The term aflatoxin(s) refers to a group of chemically related substances designated as B_1 , B_2 , G_1 , and G_2 , that are produced by certain common molds. The major member of the group is called Aflatoxin B_1 . Aflatoxin B_1 is a toxic chemical which causes liver damage in animals.

The term aflatoxin(s) also is used to designate any of several aflatoxin metabolites produced in animals receiving contaminated feed. The principal such metabolite of concern is aflatoxin M_1, a derivative of B_1 that can be formed in lactating animals and excreted in their milk.

4. Current knowledge supports the conclusion that corn containing as much as 100 ppb aflatoxin B_1 does not present a reasonable possibility of injury either to the health of mature, nonlactating livestock (beef cattle or swine) or mature poultry or to the health of humans who consume meat or eggs derived from these animals.

5. In the United States the levels of aflatoxin in corn vary from region to region and within regions, from year to year.

6. Prior to 1977, various surveys by the United States Department of Agriculture and Food and Drug Administration indicated that approximately 30% of the shelled corn grown and marketed in the Southeast had total aflatoxin levels exceeding the 20 ppb action level.

7. Food and Drug Administration surveillance of the 1977 shelled corn crop marketed in the Southeast found 64% of the samples with aflatoxin levels which exceeded 20 ppb and 40% which exceed 100 ppb.

8. Food and Drug Administration surveillance of shelled corn in the Southeast found 33% of the 1978 and 1979 crop samples to be above 20 ppb aflatoxin and 18% to be above 100 ppb.

9. Based upon preliminary data provided by states in the Southeast regarding the 1980 corn crop, 44% of the crop samples exceed 20 ppb aflatoxin and 8% exceed 100 ppb.

10. Based upon preliminary data obtained from Food and Drug Administration surveillance of the 1980 corn crop, 40% of the crop samples exceed 20 ppb and 33% exceed 100 ppb.

11. United States Department of Agriculture and Food and Drug Adminstration surveys since 1964 have found negligible aflatoxin contamination in corn harvested in the Midwest.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing statement is true and correct.

Executed on April ____, 1982.

LEONARD STOLOFF
Research Chemist
Division of Chemistry and Physics
Bureau of Foods
United States Food and Drug Administration
Washington, D.C.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 80-3110

COMMUNITY NUTRITION INSTITUTE, ET AL., PLAINTIFFS,

v.

ARTHUR HULL HAYES, JR., COMMISSIONER,
FOOD AND DRUG ADMINISTRATION, DEFENDANT.

PLAINTIFFS' RESPONSE TO DEFENDANT'S STATEMENT OF MATERIAL FACTS AS TO WHICH THERE IS NO GENUINE DISPUTE

Plaintiffs refer the Court to their statement of material facts and specifically respond to defendant's statement as follows:

1. Plaintiffs deny the factual assertions contained in the first sentence of paragraph 11, but dispute that this is a fact material to the issues involved in this suit. The question of the safety of any tolerance level should be addressed in a rulemaking proceeding in which the public is involved. The issues in this suit concern plaintiffs' effort to assure public participation in FDA's tolerance-setting activities.

2. Plaintiffs dispute that the last sentence in paragraph 12 and paragraphs 16 and 17 are material to the issues in this case, for the reasons stated in plaintiffs' opposition to defendant's motion for summary judgment at pp. 11-18.

Respectfully submitted,

/s/

Diane B. Cohn
William B. Schultz
Alan B. Morrison
2000 P Street, N.W., Suite 700
Washington, D.C. 20036
(202) 785-3704
Attorneys for Plaintiffs

May 17, 1982

Food and Drug Administration

[Docket No. 83-D-0371]

Aflatoxin-Contaminated Corn; FDA's Policy Regarding Interstate Shipment of Corn Harvested in 1983

AGENCY: Food and Drug Adminstration.

ACTION: Notice.

SUMMARY: This document announces the policy of the Food and Drug Administration [FDA] regarding interstate shipment of corn harvested in 1983 that contains aflatoxin in excess of the agency's current action level of 20 parts per billion [ppb]. Because there is a severe aflatoxin problem in the 1983 corn crop, FDA will not object to the shipment of corn containing between 20 to 100 ppb aflatoxin in interstate commerce provided reasponsible State agencies have in place a control plan that has FDA concurrence and that assures that such corn is used only in feeds for mature beef cattle, swine and poultry and that such corn is not diverted for dairy or immature animal feed use or direct human food use. As part of this policy, FDA is carrying out regulatory surveillance to ensure that State control efforts are effective.

DATES: This policy became effective November 9, 1983. This policy applies only to corn harvested in 1983 and will remain in effect until January 1985.

ADDRESS: Written comments to the Dockets Management Branch [HFA-305], Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John R. Wessel, Office of Regulatory Affairs [HFC-6], Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1815.

SUPPLEMENTARY INFORMATION: Based on the available information, the 1983 corn crop of the southeastern States shows a high incidence of aflatoxin contamination above the FDA action level of 20 ppb.

Weather conditions (i.e., drought and high humidity) similar to those which contributed to the aflatoxin problem in the Southeast also existed this year in other parts of the country. Preliminary information indicates that this year's aflatoxin problem in corn also extends beyond the Southeast.

In previous years when a severe aflatoxin/corn problem existed, the agency advised individual States that corn containing up to 100 ppb aflatoxin could be fed safely to mature nondairy livestock and poultry (46 FR 7447, January 23, 1981; 43 FR 14122, April 4, 1978). This advise was based on available scientific information which indicated then, as now, the aflatoxin levels up to 100 ppb in feed would not be detrimental to the health of mature beef cattle, swine, and poultry or result in toxicologically significant residues of aflatoxin in foods derived from these animals. Implementation of this policy was, however, contingent upon the States agreeing to exercise controls that prevented use of corn containing above 20 ppb aflatoxin for direct human food use for feeding to dairy cattle or immature animals. This control was necessary because FDA believed, and still believes, that the consumption of corn and corn products containing aflatoxin in excess of 20 ppb poses a health risk to humans and immature animals and, if fed to dairy cattle, may result in unsafe aflatoxin residues in milk.

In responding to the 1983 aflatoxin-corn situation, the agency has adopted a regulatory policy similar to that of past years. Accordingly, the agency advised the Departments of Agriculture in all States by letter dated November 9, 1983 that it will not object to corn containing between 20 and 100 ppb aflatoxin moving in interstate commerce provided responsible State officials have in place a control plan that has FDA concurrence and that assures that (1) such corn will be used only in feed for mature beef cattle, swine, and poultry; and (2) such corn

will not be diverted to feeds for dairy or immature animals or be used in the processing of corn products for human consumption.

States that choose to adopt this policy for their 1983 corn crop may design their own control plan; however, FDA has specified minimum provisions that each State control plan should contain.

Each affected State should notify FDA whether it wishes to adopt the policy and whether it is committed to and able to carry the necessary controls. States wishing to cooperate under the policy are to submit their proposed control plans to FDA for review and concurrence.

As part of a national enforcement program, FDA will be sampling corn in interstate commerce with emphasis given to corn that will be used by corn product manufacturers and dairy farms, and to States not participating in the cooperative program. FDA will also be testing milk and milk products for aflatoxin.

Because FDA's policy provides the States and the corn industry with the opportunity to channel corn containing up to 100 ppb aflatoxin into those animal feed uses that are considered safe, the agency believes it should help relieve pressures at the local level to process such corn into human food or to use it as feed for dairy animals. For this reason, FDA has also encouraged States to adopt a similar policy and control plan for corn produced and used only within their States. Additionally, States are being urged to monitor corn and corn products intended for human consumption, and to monitor milk for compliance with the 20 ppb and 0.5 ppb action levels, respectively.

Documents and correspondence related to this notice are on file with the Dockets Management Branch (address above).

Interested persons may submit comments on this notice to the Dockets Management Branch (address above). Two copies of any comments are to be submitted except that

individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 22, 1983

Joseph P. Hile,
Associate Commissioner for Regulatory Affairs.
[FR Doc. 83-31723 Filed 11-23-83; 8:45 am]
BILLING CODE 4160-01-M

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December 16, 1983

Joseph P. Hile, Associate Commissioner
for Regulatory Affairs
Dockets Management Branch (HFA-305)
Food and Drug Administration, Room 4-62
5600 Fishers Lane
Rockville, Md. 20857

Re: Aflatoxin in Corn
Docket No. 83-D-0371

Dear Mr. Hile:

These comments are submitted in response to the notice published at 48 Fed. Reg. 53175 (November 25, 1983), announcing the FDA's policy of permitting the shipment of corn containing aflatoxin levels up to 100 ppb. The comments are submitted on behalf of the Community Nutrition Institute ("CNI"), Public Citizen Health Research Group ("HRG"). Linda S. Bardot, Laura A. Rogers, and Public Voice for Food and Health Policy ("Public Voice"). All the submitters except Public Voice are plaintiffs in *Community Nutrition Institute v. Hayes,* Civil Action No. 80-3110, a case pending in the United States District Court for the District of Columbia, which challenges the FDA's policies with respect to aflatoxin. Public Voice is a public interest organization which was founded since the filing of that lawsuit and which is dedicated to promoting policies which will improve the safety and quality of the nation's food supply.

The purpose of these comments is to lodge a formal objection to the FDA's new policy of increasing the allowable levels of aflatoxin in corn to 100 ppb. We have stated the basis for our objection to the FDA's policy with respect to aflatoxin on numerous occasions. Specifically, we refer to and incorporate by reference comments filed by HRG on February 24, 1975; comments filed by CNI on October 6, 1980; comments filed by CNI and HRG on September 29, 1983; and the two legal memoranda filed by plaintiffs in the *Community Nutrition Institute v. Hayes* lawsuit. The comments are already on file with the agency, but we are attaching the legal memoranda for your information.

We wish to emphasize, as we have on numerous occasions our position that the FDA may not sanction the shipment of food with any amount of aflatoxin until it has complied with the formal rulemaking procedures in sections 406 and 701(e) of the Food, Drug and Cosmetic Act ("FDC Act"), 21 U.S.C. §§ 346, 371(e), or at least the informal rulemaking requirements of the Administrative Procedure Act ("APA"), 5 U.S.C. § 553. We hereby reiterate our request that the FDA use the formal rulemaking procedures in section 406 to establish the legal levels of aflatoxin in corn, or in the alternative, the informal rulemaking procedures in the APA. *See* Memorandum in Support of Plaintiffs' Motion for Summary Judgment, pp. 11-20.

We also belive that the FDC Act requires an opportunity for public participation before the FDA may raise the allowable level of aflatoxin in corn from 20 ppb to 100 ppb, as it has done here. As our authority for this contention, we rely on the sections of the FDC Act and the APA cited above, as well as the authorities cited in the attachments to these comments.

Sincerely yours,

/s/
William B. Schultz

Enclosures
cc: Dr. Mark Novitch, Commissioner

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Supreme Court of the United States

No. 85-664

FRANK YOUNG, COMMISSIONER OF FOOD AND DRUGS,
PETITIONER

v.

COMMUNITY NUTRITION INSTITUTE, ET AL.

ORDER ALLOWING CERTIORARI. Filed December 9, 1985.

The petition herein for a writ of certiorari to the United States Court of Appeals for the District of Columbia Circuit is granted.

U.S. GOVERNMENT PRINTING OFFICE: 1986—491-507/20513